EPA Registration No. 7173-286 vol. 1

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
X Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
7173-286	**May 13, 2009**

Term of Issuance:
Conditional

Name of Pesticide Product:
Rozol Prairie Dog Bait

Name and Address of Registrant (include ZIP Code):

R230 5-823651
1180

LiphaTech
3600 West Elm Street
Milwaukee, WI 53209

Decision #: 389136

Attention: Mr. Thomas Schmit

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that LiphaTech:

A. **within 30 days** of the Notice of Registration, submits requests for voluntary cancellation of all SLN registrations to the affected states and to EPA;

B. **within 90 Days** of this Notice, commits to conduct an Avian Reproduction Study within three (3) years of the Notice of Registration;

C. **within three (3) years** of this Notice, submits an Avian Reproduction Study;

John Hebert, Team Leader
Insecticide-Rodenticide Branch
Registration Division (7505C)

Date:
May 13, 2009

EPA Form 8570-6

D. submits a revised Confidential Statement of Formula (CSF) for this product, completely filled out, including all the ingredients; and

E. submits one (1) copy of final printed labeling, with the following label changes,

1. add the registration number to your label, "EPA Reg. No. 7173-286".

2. revise your "**PRECAUTIONARY STATEMENTS**" text, as follows, including revisions to your "**FIRST AID**" and "**Note To Physician or Veterinarian**" text and moving the "**ENDANGERED SPECIES CONSIDERATIONS**" from the "**DIRECTIONS FOR USE**" to the other "**ENVIRONMENTAL HAZARDS**:

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes, on skin, or on clothing.

All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking, chewing gum, using tobacco or using the toilet and change into clean clothing.

FIRST AID

HAVE LABEL WHEN OBTAINING TREATMENT ADVICE

IF SWALLOWED:

- Call a poison control center, doctor, or 1-800-858-7378[1] [optional] immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center, doctor, or 1-800-858-7378 [optional] for treatment advice.

[1] Also call this number for information on health concerns and pesticide incidents.

TREATMENT FOR PET POISONING

If animal eats bait, call veterinarian or 1-800-xxx-xxxx [optional] at once.

NOTE TO PHYSICIAN OR VETERINARIAN

Anticoagulant Chlorophacinone: If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. **For humans or dogs** that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

Environmental Hazards

This product is toxic for fish and wildlife. Dogs and predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present. Do not contaminate water by cleaning … treated areas.

ENDANGERED SPECIES CONSIDERATIONS: … of this product.

3. Revise your "**DIRECTIONS FOR USE**" as follows, to insure the maximum possibility of applicators following all of the required limitations and restrictions for the product's use and thereby reducing nontarget exposure:

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Dispose of product container, unused, spoiled, and unconsumed bait as specified on this label.

Use Restrictions: This product may only be used as follows:

1. **Sites/Pests:** Black-Tailed Prairie Dogs (Cynomys ludovicianus) on rangeland and adjacent noncrop areas.
2. **States:** Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming.[1]
3. **Application Method:** Hand application of bait, at least 6 inches down prairie dog burrows. This product may only be used in underground applications. **Do not apply bait on or above ground level. Treat only active burrows.**
4. **Treatment Period:** October 1 and March 15 of the following year, or before spring green-up of prairie grasses, whichever occurs later, when animals will most readily take the grain bait.
5. **Non-Applicators:** Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied.
6. **Grazing Restriction:** Do not allow livestock to graze in treated areas until after the second follow-up and when no bait is found above ground.

Site Assessment: Before applying … feces nearby.

Application Directions: Apply ¼ cup (53 gram[2] … at least 6 inches down prairie dog burrows. **Make sure** …burrow entrance.

Follow-up: Prairie Dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. The applicator must return to the site with 5 to 10 days after bait application to collect and properly dispose of any bait or dead or dying prairie dogs that may have come to the surface. Collect and bury carcasses in late afternoon, near sundown, to reduce the potential of scavenging animals finding carcasses. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes

[1] Black-Tailed Prairie Dogs no longer occur in Arizona.

[2] Retain the proposed per-burrow application amount if weight of level ¼ cup of bait averages 53 g. If not, adjust the gram- and ounce-equivalents using the following method. Weigh and average at least 10 level ¼ cups of bait. [Lee and Hyngstrom (2007) used volume measures to determine how much bait to use.]

covering and packing the hole or burrow with soil. The applicator must also return to the site 14 to 21 days after bait application to collect and properly dispose of any additional bait or dead or dying prairie dogs that may have come to the surface.
Reapplication: If prairie dog activity persists several weeks or months after…Follow all application, site assessment, and follow-up directions and use restrictions as found above.

4. Revised your "Storage and Disposal" text as follows:

STORAGE AND DISPOSAL
Do not contaminate water, food or feed by storage or disposal.
Pesticide Storage: Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.
Pesticide Disposal: Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility.
Container Handling: Nonrefillable container. Do not reuse or refill this container.
[Plastic:] Triple rinse (or equivalent) then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill; or incineration; or if allowed by state and local authorities, by burning; if burned, stay out of smoke.
[Paper] Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned stay out of smoke.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed. If you have any questions, please contact Dan Peacock by phone (703-305-5407), fax (703-308-0029), or E-Mail (peacock.dan@epa.gov).

Enclosures: 1. Stamped Label
2. Minimum Type Sizes for Final Printed Label

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

CAUTION: Keep away from humans, domestic animals and pets. Harmful if swallowed or absorbed through the skin because the material may reduce the clotting ability of the blood and cause bleeding. Avoid contact with skin, eyes or clothing. Wear shirt and long pants, shoes and socks, and chemical-resistant (such as waterproof) gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum or using tobacco. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

USER SAFETY REQUIREMENTS: Follow manufacturer's instructions for cleaning/maintaining personal protective equipment (PPE). If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

FIRST AID: Have this label with you when obtaining treatment advice.

If swallowed: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor.

If on skin or clothing: Take off contaminated clothing. Rinse skin with plenty of cool water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Note to Physician: This product may reduce the clotting ability of blood and cause hemorrhaging. If poisoning symptoms occur, intramuscular and oral administration of Vitamin K_1 may be needed. For human cases, Vitamin K_1 is antidotal at 5-10 mg (not mg/kg) for children and 10-20 mg for adults. Repeated doses may be needed (based on monitoring of prothrombin times).

Note to Veterinarian: This product contains chlorophacinone, an anticoagulant. For animals ingesting (or suspected of ingesting) bait, and/or having obvious poisoning symptoms, such as bleeding or prolonged prothrombin times, give Vitamin K_1 at 2-5 mg/kg. Repeated doses may be needed for up to 30 days based on monitoring of prothrombin times). It may be necessary to check prothrombin times every 3 days until values return to normal. In severe cases, blood transfusions may be necessary.

ENVIRONMENTAL HAZARDS: This product is toxic to fish and wildlife. Dogs and other predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten the bait. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of wastes. Runoff also may be hazardous to aquatic organisms in water adjacent to treated areas.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. This is a nonrefillable container.

Storage: Store in original container in a cool, dry place inaccessible to children and pets. Store separately from fertilizer and away from products with strong odors. Collect and properly dispose of any spillage.

Pesticide Disposal: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal: Do not reuse or refill this container. Completely empty container into application equipment. Offer for recycling if available or dispose of empty container in a sanitary landfill or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

RESTRICTED USE PESTICIDE

DUE TO HAZARD TO NONTARGET ORGANISMS

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification.

rozol®

PRAIRIE DOG BAIT

Active Ingredient: chlorophacinone	0.005%
Inert Ingredients	99.995%
Total	100.000%

EPA Reg. No. 7173-____
EPA Est. No. 7173-WI-1

KEEP OUT OF REACH OF CHILDREN

CAUTION: See side panel for additional precautionary statements.

LIPHATECH®

ACCEPTED
With COMMENTS
In EPA Letter Dated: MAY 13 2000

Liphatech, Inc.
3600 W. Elm Street
Milwaukee, WI 53209
(414) 351-1476

NET WEIGHT: 1 pounds up to 50 lbs.

Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:

7173-286

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not apply this product by any method not specified on this label.

ENDANGERED SPECIES CONSIDERATIONS: NOTICE: It is a Federal offense to use any pesticide in a manner that results in the death of an endangered species. Use of this product may pose a hazard to endangered or threatened species. Do not use this product within prairie dog towns in the range of the black-footed ferret without first contacting endangered species specialists at a U.S. Fish and Wildlife Service office. Applicators may obtain information regarding the occurrence of endangered species and use limitations for this product by calling EPA's "Endangered Species Hotline" at 1-800-447-3813 to obtain an "Interim Measures" pamphlet for your county. You may also consult your local agricultural extension office or state pesticide lead agency to determine if there are any requirements for use of this product.

Use restrictions: This product may only be used in underground applications to control black-tailed prairie dogs (*Cynomys ludovicianus*) on rangeland and noncrop areas in the states of Arizona, Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas and Wyoming. Bait must be applied at least 6 inches down prairie dog burrows. **Do not apply bait on or above ground level. Treat only active burrows.** Apply bait only between October 1 and March 15 of the following year, or before spring green-up of prairie grasses, whichever occurs later. Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied. Do not allow livestock to graze in treated areas for at least 3 days following bait application. Wear chemical-resistant gloves when handling bait or dead animals.

Site Assessment: Before applying this product, identify active prairie dog burrows by visual observation. The openings of active burrows will generally be free of leaves, seeds, other debris or spider webs, and will show freshly turned earth, and have prairie dog feces nearby.

Application: Apply 1/4 cup (53 grams or nearly 2 ounces) of bait at least 6 inches down active prairie dog burrows. **Make sure no bait is left on the soil surface at the time of application.** Applicator must retrieve and dispose of any bait that is spilled above ground or placed less than 6 inches down the burrow entrance.

Follow-up: Prairie dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. Applicator must return to the site within 5 to 10 days after bait application, to collect and properly dispose of any bait or dead or dying prairie dogs that may have come to the surface. A second carcass search and collection must be made 14 to 21 days after bait application. Carcass collection and burial should occur in late afternoon, near sundown, in order to reduce the potential of scavenging animals finding prairie dog carcasses. Carcasses buried on site must be in holes dug at least 18 inches deep, or in inactive burrows, to avoid scavenging by non-target animals. Burial includes covering and packing the hole or burrow with soil.

Reapplication: If prairie dog activity persists several weeks or months after the bait was applied, a second application may be made, by treating burrows in the same manner, time period and procedure as the first application. Follow all baiting and animal disposal and directions as above.

WARRANTY: To the extent consistent with applicable law, seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions. (02308)

revised registration notice -EIA
John Hebert to: Dan Peacock 05/14/2009 04:13 PM

I don't know if you're checking your email, but i would appreciate you looking over the revised Reg. Notice. Here are highlights of the changes I made:

1. I deleted "D" b/c i don't think we can limit any future 24c activity with this (or any other) product.

2. In env. hazards I deleted the intertidal language. Meredith pointed out that it's not appropriate for this product which i agree with.

3. i deleted the comment regarding packaging size b/c the product is RUP.

4. i qualified the grazing restriction. with your version, theoretically you can never have livestock graze in a treated area.

5. i deleted "..measured from the farthest back portion of the burrow opening" b/c i'm not sure what it means?

6. most importantly - i thought about the additional carcass search language. and i think that we don't really get anything by requiring additional searches (2 days later) if carcasses are found on the first followup. there is nothing that i saw in bill's review that indicated that if you find one carcass the site is more likely to have additional carcasses. so i decided to let the original language stand.

if i don't hear from you by noon or so on Fri i will make this final. CO already contacted me for a copy of the Reg. Notice b/c the SLN is cancelled and Lipha told them that they weren't sure if we issued it or extended the PRIA date (apparently tom doesn't know the PRIA renegotiation process very well!). i told them that it was completed on Wed and mailed out(?) but you were out and that I would try to get an electronic copy to send to them. thanks.

john

ps - before i forget...please look at the diphacinone prairie dog review(s) to check for any issues. i guess it's appropriate to have the same label language as chlorophacinone???? but i don't know what type of data (if any) scimetrics submitted.

7173-286, Notice of Registration, 5-13-2009.doc

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
7173-286	**May 13, 2009**

Term of Issuance:
Conditional

Name of Pesticide Product:
Rozol Prairie Dog Bait

Name and Address of Registrant (include ZIP Code):

LiphaTech
3600 West Elm Street
Milwaukee, WI 53209

Attention: Mr. Thomas Schmit

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that LiphaTech:

A. **within 30 days** of the Notice of Registration, submits requests for voluntary cancellation of all SLN registrations to the affected states and to EPA;

B. **within 90 Days** of this Notice, commits to conduct an Avian Reproduction Study within three (3) years of the Notice of Registration;

C. **within three (3) years** of this Notice, submits an Avian Reproduction Study;

John Hebert, Team Leader
Insecticide-Rodenticide Branch
Registration Division (7505C)

Date:
May 13, 2007

EPA Form 8570-6

D. submits a revised Confidential Statement of Formula (CSF) for this product, completely filled out, including all the ingredients; and

E. submits one (1) copy of final printed labeling, with the following label changes,

1. add the registration number to your label, "EPA Reg. No. 7173-286".

2. revise your "**PRECAUTIONARY STATEMENTS**" text, as follows, including revisions to your "**FIRST AID**" and "**Note To Physician or Veterinarian**" text and moving the "**ENDANGERED SPECIES CONSIDERATIONS**" from the "**DIRECTIONS FOR USE**" to the other "**ENVIRONMENTAL HAZARDS**:

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Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes, on skin, or on clothing.

All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking, chewing gum, using tobacco or using the toilet and change into clean clothing.

FIRST AID

HAVE LABEL WHEN OBTAINING TREATMENT ADVICE

IF SWALLOWED:

- Call a poison control center, doctor, or 1-800-858-7378[1] [optional] immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center, doctor, or 1-800-858-7378 [optional] for treatment advice.

[1] Also call this number for information on health concerns and pesticide incidents.

TREATMENT FOR PET POISONING

If animal eats bait, call veterinarian or 1-800-xxx-xxxx [optional] at once.

NOTE TO PHYSICIAN OR VETERINARIAN

Anticoagulant Chlorophacinone: If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. **For humans or dogs** that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

Environmental Hazards

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Dispose of product container, unused, spoiled, and unconsumed bait as specified on this label.

Use Restrictions: This product may only be used as follows:

1. **Sites/Pests:** Black-Tailed Prairie Dogs (Cynomys ludovicianus) on rangeland and adjacent noncrop areas.
2. **States:** Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming.[1]
3. **Application Method:** Hand application of bait, at least 6 inches down prairie dog burrows. **Do not apply bait on or above ground level. Treat only active burrows.**
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6. **Grazing Restriction:** Do not allow livestock to graze in treated areas until after the second follow-up and when no bait is found above ground.

Site Assessment: Before applying … feces nearby.

Application Directions: Apply ¼ cup (53 gram[2] … at least 6 inches down prairie dog burrows. **Make sure** …burrow entrance.

Follow-up: Prairie Dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. The applicator must return to the site with 5 to 10 days after bait application to collect and properly dispose of any bait or dead or dying prairie dogs that may have come to the surface. Collect and bury carcasses in late afternoon, near sundown, to reduce the potential of scavenging animals finding carcasses. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. The applicator must also return to the site 14 to 21 days after bait application to collect and properly dispose of any additional bait or dead or dying prairie dogs that may have come to the surface.

Reapplication: If prairie dog activity persists several weeks or months after…Follow all application, site assessment, and follow-up directions and

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[1] Black-Tailed Prairie Dogs no longer occur in Arizona.

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4. Revised your "Storage and Disposal" text as follows:

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.

Pesticide Disposal: Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container.

[Plastic:] Triple rinse (or equivalent) then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill; or incineration; or if allowed by state and local authorities, by burning; if burned, stay out of smoke.

[Paper] Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned stay out of smoke.

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Enclosures: 1. Stamped Label
2. Minimum Type Sizes for Final Printed Label

Dan Peacock, Flash Drive, 16 gb, E:\4G Dan\Doc\Word\Chlorophacinone\7173-EIA, 286\7173-286, Notice of Registration, 5-13-2009, 5-14-2009 JH Edits.doc

U.S. ENVIRONMENTAL PROTECTION AGENCY
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Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
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Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes, on skin, or on clothing.

All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

User Safety Requirements
Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking, chewing gum, using tobacco or using the toilet and change into clean clothing.

Deleted: <#>submits future amendments and new product registrations for prairie dog uses through the section 3 process of FIFRA, instead of the section 24(c) process;¶

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Deleted: <#>clarify the lowest package size of this product, which the label lists as 1 to 50 lb.¶

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FIRST AID

HAVE LABEL WHEN OBTAINING TREATMENT ADVICE

IF SWALLOWED:

- Call a poison control center, doctor, or 1-800-858-7378[1] [optional] immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.

IF ON SKIN:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center, doctor, or 1-800-858-7378 [optional] for treatment advice.

[1] Also call this number for information on health concerns and pesticide incidents.

TREATMENT FOR PET POISONING

If animal eats bait, call veterinarian or 1-800-xxx-xxxx [optional] at once.

NOTE TO PHYSICIAN OR VETERINARIAN

Anticoagulant Chlorophacinone: If swallowed, this material may reduce the clotting ability of the blood and cause bleeding. **For humans or dogs** that have ingested this product and/or have obvious poisoning symptoms (bleeding or prolonged prothrombin times), give Vitamin K_1 intramuscularly or orally.

Environmental Hazards

This product is toxic for fish and wildlife. Dogs and predatory and scavenging mammals and birds might be poisoned if they feed upon animals that have eaten this bait. Do not apply directly to water, or to areas where surface water is present. Do not contaminate water by cleaning … treated areas.

ENDANGERED SPECIES CONSIDERATIONS: … of this product.

3. Revise your "**DIRECTIONS FOR USE**" as follows, to insure the maximum possibility of applicators following all of the required limitations and restrictions for the product's use and thereby reducing nontarget exposure:

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DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
2. Dispose of product container, unused, spoiled, and unconsumed bait as specified on this label.

Use Restrictions: This product may only be used as follows:

1. **Sites/Pests:** Black-Tailed Prairie Dogs (Cynomys ludovicianus) on rangeland and adjacent noncrop areas.
2. **States:** Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming.[1]
3. **Application Method:** Hand application of bait, at least 6 inches down prairie dog burrows. **Do not apply bait on or above ground level. Treat only active burrows.**
4. **Treatment Period:** October 1 and March 15 of the following year, or before spring green-up of prairie grasses, whichever occurs later, when animals will most readily take the grain bait.
5. **Non-Applicators:** Do not allow children, pets, domestic animals or persons not involved in the application to be in the area where the product is being applied.
6. **Grazing Restriction:** Do not allow livestock to graze in treated areas until after the second follow-up and when no bait is found above ground.

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Site Assessment: Before applying … feces nearby.

Application Directions: Apply ¼ cup (53 gram[2] … at least 6 inches down prairie dog burrows. **Make sure** …burrow entrance.

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Deleted: (measured from the farthest back portion of the burrow opening)

Follow-up: Prairie Dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. The applicator must return to the site with 5 to 10 days after bait application to collect and properly dispose of any bait or dead or dying prairie dogs that may have come to the surface. Collect and bury carcasses in late afternoon, near sundown, to reduce the potential of scavenging animals finding carcasses. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. The applicator must also return to the site 14 to 21 days after bait application to collect and properly dispose of any additional bait or dead or dying prairie dogs that may have come to the surface.

Deleted: If the applicator finds bait or carcasses on the surface during the 5-10 day initial post-application search, then applicator must return to the site within two (2) days of the initial search for a follow-up search for bait and carcasses.

Reapplication: If prairie dog activity persists several weeks or months after…Follow all application, site assessment, and follow-up directions and

[1] Black-Tailed Prairie Dogs no longer occur in Arizona.

[2] Retain the proposed per-burrow application amount if weight of level ¼ cup of bait averages 53 g. If not, adjust the gram- and ounce-equivalents using the following method. Weigh and average at least 10 level ¼ cups of bait. [Lee and Hyngstrom (2007) used volume measures to determine how much bait to use.]

use restrictions as found above.

Deleted: ... directions

4. Revised your "Storage and Disposal" text as follows:

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STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.

Pesticide Disposal: Wastes resulting from the use of this product may be placed in trash or delivered to an approved waste disposal facility.

Container Handling: Nonrefillable container. Do not reuse or refill this container.

[Plastic:] Triple rinse (or equivalent) then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill; or incineration; or if allowed by state and local authorities, by burning; if burned, stay out of smoke.

[Paper] Dispose of empty container by placing in trash, at an approved waste disposal facility or by incineration or, if allowed by state and local authorities, by burning. If burned stay out of smoke.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed. If you have any questions, please contact Dan Peacock by phone (703-305-5407), fax (703-308-0029), or E-Mail (peacock.dan@epa.gov).

Enclosures: 1. Stamped Label
2. Minimum Type Sizes for Final Printed Label

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
7173-286	**May 13, 2009**

Term of Issuance:
Conditional

Name of Pesticide Product:
Rozol Prairie Dog Bait

Name and Address of Registrant (include ZIP Code):

LiphaTech
3600 West Elm Street
Milwaukee, WI 53209

Attention: Mr. Thomas Schmit

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that LiphaTech:

A. **within 30 days** of the Notice of Registration, submits requests for voluntary cancellation of all SLN registrations to the affected states and to EPA;

B. **within 90 Days** of this Notice, commits to conduct an Avian Reproduction Study within three (3) years of the Notice of Registration;

C. **within three (3) years** of this Notice, submits an Avian Reproduction Study;

John Hebert, Team Leader
Insecticide-Rodenticide Branch
Registration Division (7505C)

Date:
May 13, 2007

EPA Form 8570-6

D. submits a revised Confidential Statement of Formula (CSF) for this product, completely filled out, including all the ingredients; and

E. submits one (1) copy of final printed labeling, with the following label changes,

1. add the registration number to your label, "EPA Reg. No. 7173-286".

2. revise your "**PRECAUTIONARY STATEMENTS**" text, as follows, including revisions to your "**FIRST AID**" and "**Note To Physician or Veterinarian**" text and moving the "**ENDANGERED SPECIES CONSIDERATIONS**" from the "**DIRECTIONS FOR USE**" to the other "**ENVIRONMENTAL HAZARDS**:

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

CAUTION: Harmful if swallowed or absorbed through the skin because it may reduce the clotting ability of blood and cause bleeding. Keep away from children, domestic animals and pets. Do not get in eyes, on skin, or on clothing.

All handlers (including applicators) must wear shoes plus socks, and gloves. Any person who retrieves carcasses or unused bait following application of this product must wear gloves.

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry. Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash hands thoroughly after applying bait and before eating, drinking, chewing gum, using tobacco or using the toilet and change into clean clothing.

FIRST AID

HAVE LABEL WHEN OBTAINING TREATMENT ADVICE

IF SWALLOWED:

- Call a poison control center, doctor, or 1-800-858-7378[1] [optional] immediately for treatment advice.
- Have a person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor.

IF ON SKIN:

- Take off contaminated clothing.
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- Call a poison control center, doctor, or 1-800-858-7378 [optional] for treatment advice.

[1] Also call this number for information on health concerns and pesticide incidents.

TREATMENT FOR PET POISONING

If animal eats bait, call veterinarian or 1-800-xxx-xxxx [optional] at once.

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READ THIS LABEL and follow all use directions and precautions. Only use for sites, pests, and application methods specified on this label.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help prevent accidents:

1. Store product not in use in a location out of reach of children and pets.
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Use Restrictions: This product may only be used as follows:

1. **Sites/Pests:** Black-Tailed Prairie Dogs (Cynomys ludovicianus) on rangeland and adjacent noncrop areas.
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Site Assessment: Before applying … feces nearby.

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Follow-up: Prairie Dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. The applicator must return to the site within 5 to 10 days after bait application to collect and properly dispose of any bait or dead or dying prairie dogs that may have come to the surface. Collect and bury carcasses in late afternoon, near sundown, to reduce the potential of scavenging animals finding carcasses. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. The applicator must also return to the site 14 to 21 days after bait application to collect and properly dispose of any additional bait or dead or dying prairie dogs that may have come to the surface.

Reapplication: If prairie dog activity persists several weeks or months

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[1] Black-Tailed Prairie Dogs no longer occur in Arizona.

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after…Follow all application, site assessment, and follow-up directions and use restrictions as found above.

4. Revised your "Storage and Disposal" text as follows:

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage: Store only in original container in a cool, dry place inaccessible to children and pets. Keep containers closed and away from other chemicals.

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Container Handling: Nonrefillable container. Do not reuse or refill this container.

[Plastic:] Triple rinse (or equivalent) then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill; or incineration; or if allowed by state and local authorities, by burning; if burned, stay out of smoke.

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If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

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U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
X Registration
__ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
7173-286	May 13, 2009

Term of Issuance:
Conditional

Name of Pesticide Product:
Rozol Prairie Dog Bait

Name and Address of Registrant (include ZIP Code):

LiphaTech
3600 West Elm Street
Milwaukee, WI 53209

Attention: Mr. Thomas Schmit

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John Hebert, Team Leader
Insecticide-Rodenticide Branch
Registration Division (7505C)

Date:
May 13, 2007

EPA Form 8570-6

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[Plastic:] Triple rinse (or equivalent) then offer for recycling or reconditioning; or puncture and dispose of in a sanitary landfill; or incineration; or if allowed by state and local authorities, by burning; if burned, stay out of smoke.

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Enclosures: 1. Stamped Label
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prairie dog bait

John Hebert to: Dan Peacock 05/15/2009 05:35 PM

History: This message has been replied to.

Dan - here is the Reg. Notice. I added one more comment to it from the version i sent yesterday. Please finalize (and make sure it has the 5/13 date) and email it with the stamped label to both Tom Schmitt and Laura Quakenbush in Colorado. Here is Laura's email:

"Quakenbush, Laura" <Laura.Quakenbush@ag.state.co.us>

thanks,
john

7173-286, Notice of Registration, 5-13-2009.doc

Fw: Rozol Prairie Dog Bait, 7173-EIA
John Hebert to: Dan Peacock 05/12/2009 04:44 PM

Dan - I don't think those studies were considered in EFED's RA. not sure what happened. your bean sheet clearly lists them??? I spoke to Jean Holmes about it but she doesn't know but is checking. I looked at Bill's review (of the field study) and found that of the several hundred acres and 10,000+ burrows treated there were only 10 carcasses found. also, there was little bait found above ground. based on that meredith and i decided to leave the language proposed by Lipha on the label regarding followup carcass and bait search alone. unfortunately, we can't renegotiate b/c EFED didn't review the studies. we'll have to rely on bill's review (i think we're lucky to have that). so....we'll just have to register w/comments. we can discuss this when i get in tomorrow morning.

thanks,
john

----- Forwarded by John Hebert/DC/USEPA/US on 05/12/2009 04:29 PM -----

From:	John Hebert/DC/USEPA/US
To:	Dan Peacock/DC/USEPA/US@EPA
Date:	05/07/2009 12:18 AM
Subject:	Re: Rozol Prairie Dog Bait, 7173-EIA

Dan - here are my comments. they may seem a little disjointed b/c i'm doing this from home and i don't have a paper copy of anything. here goes:

1. by requiring searches every 2 days until no carcasses or bait is found....could it be possible that you may have a situation right after baiting that you don't find bait pushed above ground (maybe b/c it's all has mostly been eaten?) and the chlorophacinone hasn't started working yet? so theoretically you might be able to stop observations after the first two days? i think we should add a minimum requirement...maybe that searches must continue for at least 10 days.

2. i don't think i agree with EFED concerns regarding the black footed ferret. it's my understanding that the reintro. programs are so tightly controlled/managed that there is little chance that they would be introduced in an area where prairie dogs are being baited. and plus the endangered species language would prevent baiting in bff areas. but i do agree with you that "noncrop areas" is too broad.

3. regarding the avian repro study, so EFED did review the waiver and decided not to accept it? i think we should make this a condition of registration. we should stress that this has been a requirement from the RED and that it has been a gap for 10+ years. that way we won't need committment within 90 days from registration.
4. i'm having trouble downloading the label so i don't know what it says now about collecting non-target carcasses. but i wonder if we put a collection requirement would "proper authorities" really be able to accept them and do anything with the samples. and exactly who are these authorities? i agree with you that we should not but this on the label.

5. i made a few minor comments on your letter. it's attached.

6. thanks for working on this. i'll be checking email probably thurs nite if you have any comments, etc.

john

-----Dan Peacock/DC/USEPA/US wrote: -----

To: John Hebert/DC/USEPA/US@EPA

From: Dan Peacock/DC/USEPA/US
Date: 05/06/2009 07:46AM
Subject: Rozol Prairie Dog Bait, 7173-EIA

John,

I have finished my comments on this pending product. I will be in the office a little after 9AM.

This table is the justification for RD's Response to EFED's Risk Concerns

---

Here is LiphaTech's proposed label:

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

Chlorophacinone on prairie dogs
John Hebert to: Jean Holmes, Jonathan Angier 05/11/2009 12:36 PM
Cc: Meredith Laws, Dan Peacock

Jean/Jonathan - EFED did a RA for this use under DP #350010 and according to OPPIN it was closed out on Nov. 12. According to the bean sheet there were 3 studies sent as part of the review package. I can't find any mention of these studies in the RA. Do you know if these studies were reviewed and more importantly, were taken into consideration? The MRIDs for the three studies are:

47333601
47333602
47333603

The PRIA date for this action is Wed so I would appreciate a quick reply.

Thanks,
John Hebert
308-6249

conversation w/tom schmitt

John Hebert to: Dan Peacock 05/08/2009 05:36 PM

i had a loud conversation with schmitt today about the prairie dog label. i told him that we wanted the label to have the same (every 2 day) carcass search language, as found on the slns. he said that the study/data he submitted shows that you don't find any carcasses above ground. according to OPPIN you sent 3 studies to EFED, but i can't find any mention of them in their risk assessment? do you know if these were reviewed? also, tom complained that we're waiting until the last minute to give him substantial label changes that he doesn't agree with. i think he has a point. i bet we'll end up extending this one. please let me know if you know anything about these studies (one was the field efficacy/hazards).

john

Request for Help:
7173-EIA, Input into Revised Use Directions and Question about Review of Avian Reproduction Waiver, PRIA Due Date Wed, May 13, 2009

Dan Peacock to: Bill Jacobs, Ron Dean 05/07/2009 09:05 AM

Bill and Ron,

I drafted a letter to LiphaTech regarding their proposed new use, Rozol Prairie Dog Bait, EPA File Symbol 7173-EIA that my Team Leader, John Hebert had made some minor changes and **had posed some important questions** about which I **need input** before we can send out the letter:

1. my **proposed revisions to the use directions** and
2. status of EPA's review of their waiver request of the avian reproduction study (requested in a DCI (about 2000) authorized in the 1998 Rodenticide Cluster RED. John wanted to know if they had it. Assuming that it was in a risk assessment, they would.

[I would have liked for all of us to meet around a table to discuss my 1) proposed conditions of registration and 2) proposed use directions, which tried to harmonize a wide range of conflicting SLN labels and LiphaTech's much more liberal proposed label. However, I work at home today and will not be in the office until Wed at noon, and John is out of the office today (Thurs). So the remaining option is E-Mail.]

Request:

Can both of you "put your head's together" and give me feed back on my proposed use directions by 5 PM today?
When I get back, I can give you a beans in OPPIN if that helps

You will find my proposed conditions of registration and label changes (especially the use directions) the following edited version of my draft May 6 letter:

7173-EIA, prairie dog use, 5-6-2009, JHebert Edits.doc

The following table, which I shared with John, contains my justification for RD Response to EFED Risk Concerns.

Justification for RD Mitigation Resp to EFED Risks Conc, 5-5-2009.doc

This is LiphaTech's proposed label:

7173-EIA, imaged proposed label.pdf

Questions:

A. Use Directions

1. What is the proper criteria for terminating carcasses and bait searches, which is critical for mitigating

nontarget exposure?

Problem: Approved state and LiphaTech proposed labels and proposals by me and John Hebert are "all over the map":

Search 1 for bait/carcasses **(5 - 10 days)**; Search 2 for carcasses **(14 - 21 days)**, no other requirement **(Co** Proposed Federal Label)

Search every 1-2 days, beginning 1-2 days after application, for bait/carcasses until no carcasses found **(many SLN labels)**

Search every 1-2 days, beginning 1-2 days after application **for 14 days,** for bait/carcasses until no carcasses found **(CO SLN label)**

Search every 1-2 days, beginning 2 days after application, but no criteria for cessation of searches. **(EFED Risk Ass, p2)**

Search,beginning 2 days after application for **2 consecutive negative bait/carcass searches. (DPeacock's Initial Proposal)**

(I was concerned that persons were stop searching on Day 2 and concerned about irregular dying patterns from a slow acting active.

I do not know if 2 consecutive bait/carcass negative searches would be enough. **Here is where the efficacy data might help us.**

John Hebert had suggested " I think we should add a minimum requirement...maybe that searches must continue for at least 10 days." (That would be 5 searches.)

[SLN Labels are in my Chlorophacinone Label book and the administrative jackets are in the Central Overhead Bin.]

My Initial Proposed "Follow-Up" and "Reapplication" Directions:

Follow-up: Prairie Dogs that have eaten this bait will begin to die off in 4 to 5 days after they eat a lethal amount. Applicator must return to the site every two (2) days after application, to collect and properly dispose of any bait or dead or dying prairie dogs that may have come to the surface. Collect and bury carcasses in late afternoon, near sundown, to reduce the potential of scavenging animals finding carcasses. Bury carcasses on site in holes dug at least 18 inches deep or in inactive burrows (no longer being used by prairie dogs or other species) to avoid non-target animal scavenging. Burial includes covering and packing the hole or burrow with soil. **Continue returning to the site every two (2) days until no carcasses or bait are found for two consecutive searches.**
Reapplication: If prairie dog activity **persists 30 days after completion of bait application and follow-up** (two consecutive searches without finding carcasses or bait), make second (final) application during the "**Treatment Period**", following all application and follow-up directions as above.

B. Status of LiphaTech Avian Reproduction Waiver [I believe originally submitted with last amendment for Rozol Vole Bait, 7173-242.]

Questions:

Did EFED complete its review? [I am at home and have no access to these files.]
Is it a separate document or part of the last 7173-242 (Rozol Vole Bait) Risk Assessment)?
[Note: if it were part of the risk assessment, then the co would already have our review.]

Next Steps

If we can come to some type of concensus or compromise, then I can pass along a recommendation to John Hebert, who could then forward a final version of the letter to LiphaTech on Friday.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

Re: Rozol Prairie Dog Bait, 7173-EIA

Dan Peacock to: John Hebert 05/07/2009 10:07 PM

Cc: Bill Jacobs, Ron Dean

John,

I sought 2nd opinions about my proposed use directions from Ron Dean and Bill Jacobs, especially the criteria for terminating bait and carcass searches.

Ron Dean (EFED) liked the mitigation but did not offer any improvements. Tomorrow is his last day at EPA.
I have not heard from Bill yet. I thought that the efficacy data could inform our decision. You might ask him if he had any recommendations.
As you can see from the analysis below, there has been a lot of suggestions on the topic:

A. Use Directions

1. What is the proper criteria for terminating carcasses and bait searches, which is critical for mitigating nontarget exposure?

Problem: Approved state and LiphaTech proposed labels and proposals by me and you are "all over the map":

Search 1 for bait/carcasses **(5 - 10 days)**; Search 2 for carcasses (**14 - 21 days**), no other requirement (**Co** Proposed Federal Label)
Search every 1-2 days, beginning 1-2 days after application, for bait/carcasses until no carcasses found (**many SLN labels)**
Search every 1-2 days, beginning 1-2 days after application **for 14 days**, for bait/carcasses until no carcasses found (**CO SLN label**)
Search every 1-2 days, beginning 2 days after application, but no criteria for cessation of searches. (**EFED Risk Ass, p2**)

Search,beginning 2 days after application for **2 consecutive negative bait/carcass searches. (DPeacock's Initial Proposal)**

(I was concerned that persons would stop searching on Day 2 and concerned about irregular dying patterns from a slow acting active.
I do not know if 2 consecutive bait/carcass negative searches would be enough. **Here is where the efficacy data might help us.**

You had suggested " I think we should add a minimum requirement...maybe that searches must continue for at least 10 days." (That would be 5 searches.)

So it is up to you how you would like to handle the draft letter. I have sent nothing to the co as yet. Your best bet might be to get Bill's input before deciding what to do. Good luck.

With regard to the status of EFED's review of the avian repro study, I believe that they reviewed it as part of a risk assessment for Rozol Vole Bait (7173-242) but need to verify that when I return Wed.

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029

E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

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John Hebert | Dan - here are my comments. they may seem a... | 05/07/2009 12:18:14 AM

From: John Hebert/DC/USEPA/US
To: Dan Peacock/DC/USEPA/US@EPA
Date: 05/07/2009 12:18 AM
Subject: Re: Rozol Prairie Dog Bait, 7173-EIA

Dan - here are my comments. they may seem a little disjointed b/c i'm doing this from home and i don't have a paper copy of anything. here goes:

1. by requiring searches every 2 days until no carcasses or bait is found....could it be possible that you may have a situation right after baiting that you don't find bait pushed above ground (maybe b/c it's all has mostly been eaten?) and the chlorophacinone hasn't started working yet? so theoretically you might be able to stop observations after the first two days? i think we should add a minimum requirement...maybe that searches must continue for at least 10 days.

2. i don't think i agree with EFED concerns regarding the black footed ferret. it's my understanding that the reintro. programs are so tightly controlled/managed that there is little chance that they would be introduced in an area where prairie dogs are being baited. and plus the endangered species language would prevent baiting in bff areas. but i do agree with you that "noncrop areas" is too broad.

3. regarding the avian repro study, so EFED did review the waiver and decided not to accept it? i think we should make this a condition of registration. we should stress that this has been a requirement from the RED and that it has been a gap for 10+ years. that way we won't need committment within 90 days from registration.
4. i'm having trouble downloading the label so i don't know what it says now about collecting non-target carcasses. but i wonder if we put a collection requirement would "proper authorities" really be able to accept them and do anything with the samples. and exactly who are these authorities? i agree with you that we should not but this on the label.

5. i made a few minor comments on your letter. it's attached.

6. thanks for working on this. i'll be checking email probably thurs nite if you have any comments, etc.

john

-----Dan Peacock/DC/USEPA/US wrote: -----

To: John Hebert/DC/USEPA/US@EPA
From: Dan Peacock/DC/USEPA/US
Date: 05/06/2009 07:46AM
Subject: Rozol Prairie Dog Bait, 7173-EIA

John,

I have finished my comments on this pending product. I will be in the office a little after 9AM.

This table is the justification for RD's Response to EFED's Risk Concerns

---

Here is LiphaTech's proposed label:

Thank You,

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
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Re: Request for Help:
7173-EIA, Input into Revised Use Directions and Question about Review of Avian Reproduction Waiver, PRIA Due Date Wed, May 13, 2009

Ron Dean to: Dan Peacock 05/07/2009 11:27 AM
Cc: Bill Jacobs, Jonathan Angier, Tom Bailey, Jean Holmes

Hi Dan:

These changes look really good to me. Especially not applying the bait where the target organism does not exist and tightening up the use areas and monitoring.

Also, please be aware that as of tomorrow I will no longer be an employee of EFED, I have accepted a position at NOAA Marine Fisheries. I will still be monitoring e-mail until my account is disabled, but should not receive any CBI info.

Thanks,

-Ron

Ron Dean
Biologist
US Environmental Protection Agency
2777 S. Crystal Dr.
Arlington, VA 22202
Mail Code: 7507P
703.308.5892

Dan Peacock Bill and Ron, I drafted a letter to LiphaTech rega... 05/07/2009 09:05:26 AM

From: Dan Peacock/DC/USEPA/US
To: Bill Jacobs/DC/USEPA/US@EPA, Ron Dean/DC/USEPA/US@EPA
Date: 05/07/2009 09:05 AM
Subject: Request for Help:
7173-EIA, Input into Revised Use Directions and Question about Review of Avian Reproduction Waiver, PRIA Due Date Wed, May 13, 2009

Bill and Ron,

I drafted a letter to LiphaTech regarding their proposed new use, Rozol Prairie Dog Bait, EPA File Symbol 7173-EIA that my Team Leader, John Hebert had made some minor changes and **had posed some important questions** about which I **need input** before we can send out the letter:

1. my **proposed revisions to the use directions** and
2. status of EPA's review of their waiver request of the avian reproduction study (requested in a DCI (about 2000) authorized in the 1998 Rodenticide Cluster RED. John wanted to know if they had it. Assuming that it was in a risk assessment, they would.

[I would have liked for all of us to meet around a table to discuss my 1) proposed conditions of registration and 2) proposed use directions, which tried to harmonize a wide range of conflicting SLN labels and LiphaTech's much more liberal proposed label. However, I work at home today and will not be in the office until Wed at noon, and John is out of the office today (Thurs). So the remaining option is E-Mail.]

Request:

Re: 7173-EIA, Discussion of Draft Letter, Action Due Next Wed, May 13, 2009

Dan Peacock to: John Hebert 05/06/2009 01:09 PM

John,

Thanks for info on your schedule. Mine is as follows:

> I will be here today, working at home Thurs AM (7th), out of town Fri - Tues (8th thru 12th), and back in the office next Wed PM, the due date for this action, **May 13, 2009.**

So, since we will not be working at the same time after today, until next Wed at noon, would you have time to go over the draft letter later this PM so that we potentially send it out today and give the co time to get a clean label and revised forms prior to issuance of the Notice?

I can go over the points where LiphaTech might push back. That's why I attached the table with EFED's Risk Concerns, RD's Proposed Mitigation, and a Justification. With a sensitive use, such as this one, I thought it would be worth the time to provide such a document since, over time, we could get challenges from multiple sources about our decision and its components.

Daniel B. Peacock, Biologist
Tel: 703-305-5407
Fax: 703-308-0029
E-Mail: peacock.dan@epa.gov

Addresses:
United States Postal Service (USPS): USEPA, Insecticide-Rodenticide Branch, Registration Division (7504P), 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001

Courier Deliveries: USEPA, Insecticide-Rodenticide Branch, Registration Division, Room S-4900, One Potomac Yard, 2777 Crystal Drive, Arlington, VA 22202

John Hebert Thanks for the update. but, just fyi i'll be out tom... 05/06/2009 12:02:52 PM

From: John Hebert/DC/USEPA/US
To: Dan Peacock/DC/USEPA/US@EPA
Date: 05/06/2009 12:02 PM
Subject: Re: 7173-EIA, Status

Thanks for the update. but, just fyi i'll be out tomorrow and back in on friday.

john

Dan Peacock John, I have just completed the draft letter to Lip... 05/05/2009 05:08:01 PM

Justification for RD Mitigation Responses to EFED Risks Concerns Rozol Prairie Dog Bait, EPA File Symbol 7173-RIA (286)		
EFED Risks Concerns	**RD Mitigation Responses**	**Justification**
1. Proposed label includes the State of Arizona, where the Black-Tailed Prairie Dog no longer occurs. (p2). EFED says that excluding AZ would greatly reduce accidental misuse and potential for primary and secondary exposure. (p2)	1. RD will require Co to delete AZ as an acceptable state for application.	1. We cannot justify including states where target species no longer exists. There is no benefit and only potential additional risk. [If the co documented the presence of this species in AZ, then we would have to reconsider this exclusion.
2. Proposed label only requires 2 carcass searches at 5-10 and 14-21 days after application where past state labels required carcass searches every 1-2 days, beginning 2 days after application. (p2) [DBPeacock Note: One SLN (CO-060009) required "1 to 2 day" searches for a minimum of 14 days, and longer if carcasses were still found.] EFED states that returning to intervals of carcass searches every 1-2 days, beginning 2 days after application will reduce secondary exposure to nontarget species. (p2)	2. RD will require Co to have not only carcass, but bait, searches, beginning 2 days after application and to continue every 2 days, until no carcasses or bait are found for two consecutive searches.	2. State labels required searches for both **bait** and carcasses. **Bait searches** are important because accessible bait could produce both primary and secondary poisoning. Bait can still be kicked out of the burrows and onto the ground above as long as there are surviving prairie dogs. The proposed label requires a search strategy of 2 consecutive negative searches, 2 days apart, prior to cessation of searches, because it recognizes the likely unpredictable pattern of death and from a slow acting toxicant, Chlorophacinone. Some state labels required searches to begin "1 to 2" days after application and every "1 to 2 days" until no dead animals are found. However, the proposed revision includes the mandatory 2 day interval (not 1 or 2 days) because such searches are time consuming and expensive and applicators are only going to do what is mandatory. If an applicator did a search at 2 days and found no dead animals (which would not be expected for 4-5 days), he could legally stop future searches. Therefore, there must be at least 2 searches covering a span of 4 days.

		The proposed search strategy (requiring 2 consecutive bait- and carcass-free searches prior to terminating searches) would cover the situation where animals started appearing on Day 5 because some bait would likely be found on Search 1 (Day 2), requiring at least 2 more searches, Search 2 (Day 4) and Search 3 (Day 6) when animals appearing above ground on Day 5 would be found. The mandatory 14 day searches for CO-060009 seemed excessive if carcasses or bait were no longer being found after 4 days.
3. Proposed label provides vague instructions for "reapplications", suggesting that activity from an unsuccessful treatment could persist for weeks to months after 1st application. EFED is concerned that such vague text could result in reapplications before carcass searches are completed after the 1st application, resulting in an increase exposure to nontarget species. (p 2)	3. Proposed label clarifies the vague text as follows: a. There may only be one reapplication. b. Applicator must wait thirty days after the end of the 1st application and follow-up (defined as two consecutive searches without finding carcasses or bait). to make second (final) application during the "Treatment Period" and must follow all application and follow-up directions, as before.	3. According to the data, this bait formula normally works with a single application so reapplication is not expected to be the norm. Two applications is the maximum mentioned on any state labels. The 30 day interval between conclusion of follow-up of Application 1 and the 2nd application will prevent overlapping treatments and finsures enough time passes to gage the effect of the 1st treatment. If animals are not accepting the bait, then the control officials would have to consider using another pesticide, like Zinc Phosphide or Diphacinone.
4. Proposed uses will pose primary risks to nontarget mammals and birds exceeding EPA's Levels of Concern (LOC). (p2) Secondary/Tertiary risk to mammals is also likely, including endangered and threatened species under the	4. In addition to the label improvements "1 to 3" above, the "Use Restrictions" in the "**DIRECTIONS FOR USE**" have been subdivided and bulleted for clearer communication of restrictions.	4. Making text clearer will improve likelihood that restrictions will be understood and followed and easier for enforcement, if not followed.

ESA. (p2)		
5.EFED is concerned that reduction of black-tailed prairie dog populations will reduce the prey base of the endangered black-footed ferret, which the USFWS is trying to reintroduce in its historic range and will prevent such programs from being successful. (p3-4)	5. The revised label will modify the label sites from "rangeland and noncrop areas" to "rangeland and adjacent noncrop areas areas".	5. This change focuses properly on noncrop sites adjacent to rangeland where prairie dogs can invade rangeland and become pests by consuming food for livestock and by being a hazard for livestock. The product should not be used to eradicate all black-tailed prairie dogs in other noncrop areas where they are not pests. The term, "noncrop areas" is too vague. If there are other specific "noncrop areas" where prairie dogs are a problem, the co any propose them and EPA can consider them on their merits.
6. Key Uncertainties & Data Gaps **Avian Reproduction** EFED is concerned that there are no data to assess potential reproductive impairment to any species groups, but especially birds. (p4)	6. RD would propose to require, as a condition of registration, an avian reproduction study to be submitted within 3 years of approval of the black-tailed prairie dog use, which the co would have to commit to conducting within 90 days of approval.	6. The EPA has long recognized the potential for lethal and sublethal exposure to birds from field uses of anticoagulants, based on data and incidents. EPA originally requested an avian reproduction study for Chlorophacinone in the 1998 Rodenticide Cluster RED, along with other studies.[1] I recently asked SRRD for the status of the studies requested but so far they have been unable to provide a status of this or other studies requested in the DCIs. While EPA did not require the study prior to issuance of the RED, Co are suppose to conduct the requested studies or face suspension of affected products. RD later requested the study as part of an approval of Rozol Vole Bait, EPA Reg. No. 7173-242. The co requested a waiver of the study. EFED has not accepted

[1] We need to revisit the Generic DCI's of the Rodenticide Cluster and Zinc Phosphide RED, determine the status of the original data, determine which data are still needed and what new data may be needed, and determine our next steps. Such a review and follow-up of the Generic DCIs would prevent us from singling out individual actives and avoid claims of creating an "unlevel playing field".

		the rationale for the waiver and still considering the study a data gap. Since the 1998 Rodenticide Cluster, field uses of Chlorophacinone have expanded, providing additional potential to birds. Additional field uses will be expected. High profile pesticide incidents with Chlorophacinone have been reported in Artichoke fields in CA. The USFWS has expressed concerns about the potential for primary and secondary poisoning due to anticoagulants such as Chlorophacinone.
7. **Identification of Nontarget Kills, Analysis of Tissue Residues, and Reporting of Incidents** EFED has recommended that that applicators 1. collect nontarget animals and turn them into proper authorities for identification and tissue-residue analysis to determine if animal was exposed to Chlorophacinone and 2. report the results reported to appropriate sate and Federal Agencies (USFWS and EPA). (p2)	Discussion needed before adopting any course of action.	This is a laudable recommendation and would normally be automatically followed if a government agency were sponsoring a prairie dog control program. However, if we made the recommendation a 1) label requirement or 2) a condition of registration, then the co would probably allege that we were singling out their product. The subject might be one to discuss. Perhaps a separate E-Mail reminder to the company of their responsibility to monitor, investigate, and report nontarget incidents, of which they become aware, would be a possibility. Being a good steward of their product and taking corrective action, when problems arose, might allow the co to take corrective action (modifying the label) and avoid future regulatory action.

Registered Chlorophacinone Products, May 4, 2009						
Reg	**Name**	**Date Reg**	**Rest ?**	**Co #**	**Co Name**	**% Active**
56-56	EATON ANS MICE FEED BOX	01-Jul-1988	N	56	EATON	.005
56-58	EAT AC FORMULA 90 ROD	10-Feb-1989	N	56	EATON	.005
56-69	EAT ANS FOR RATS FEED BOX	19-Oct-1995	N	56	EATON	.005
56-70	JT EATON AC FOR 90 RTU ROD	19-Oct-1995	N	56	EATON	.005
7173-75	ROZOL ROD TECH POWDER	10-Jun-1971	N	7173	LIPHAT.	98.9
7173-113	ROZOL TRACKING POWDER	22-Jan-1973	Y	7173	LIPHAT	.2
7173-151	ROZOL PELLETS	24-Jan-1975	N	7173	LIPHAT.	.005
7173-172	ROZOL BLUE TR POWDER	18-Sep-1978	Y	7173	LIPHAT	.2
7173-184	ROZOL POCKET GOPHER BAIT	18-Aug-1982	N	7173	LIPHAT	.005
7173-219	ROZOL ROD 2% DRY CONC	10-Dec-1997	N	7173	LIPHAT	2
7173-242	ROZOL VOLE BAIT	09-Nov-2005	Y	7173	LIPHAT.	.005
7173-243	ROZOL MINI BLOCKS	14-Feb-2005	N	7173	LIPHAT.	.005
7173-244	ROZOL POCKET GOPHER BT II	02-Mar-2005	Y	7173	LIPHAT	.005
7173-251	ROZOL PARAFFIN BLOCK	05-Mar-2007	N	7173	LIPHAT	.005
7173-252	ROZOL PELLETS PLACE PKS	05-Feb-2007	N	7173	LIPHAT	.005
7173-287	CHLOROPHACINONE BT STA	09-Jan-2009	N	7173	LIPHAT	.005
CA060006	ROZOL PELLETS	05-Jul-2006	N	7173	LIPHAT	.005
CA890023	ROD BT CHL TR GR (0.005%)	29-Sep-2008	N	59623	CDFA	.005
CA890024	ROD BT – CHL TR GR (0.01%)	29-Sep-2008	N	59623	CDFA	.01
CA930022	ROD BT CHLOROPHACINONE	29-Sep-2008	N	59623	CDFA	.01
CO060009	ROZOL PRAIRIE DOG BAIT	03-Nov-2006	N	7173	LIPHAT	.005
HI080001	ROZOL MINI BLOCKS	16-Mar-2009	N	7173	LIPHAT	.005
HI080002	ROZOL PELLETS	19-Feb-2009	N	7173	LIPHAT.	.005
KS070003	ROZOL PRAIRIE DOG BAIT	02-Oct-2007	N	7173	LIPHAT	.005
MT000007	ROZOL GRD SQUIR OAT BAIT	07-Sep-2000	N	7173	LIPHAT	0
MT000007	ROZOL GRD SQUIR OAT BAIT	07-Sep-2000	N	7173	LIPHAT	.005
NE060001	ROZOL PRAIRIE DOG BAIT	06-Mar-2006	N	7173	LIPHAT.	.005
OK080002	ROZOL PRAIRIE DOG BAIT	29-Jan-2008	N	7173	LIPHAT	.005
OR060026	ROZOL PELLETS	20-Jul-2007	N	7173	LIPHAT	.005
TX070008	ROZOL PRAIRIE DOG BAIT	7-May-2007	N	7173	LIPHAT	.005
WA060019	ROZOL PELLETS	26-Sep-2006	N	7173	LIPHAT.	.005
WA070019	ROZOL VOLE BAIT	10-Jan-2008	N	7173	LIPHAT.	.005
WY070005	ROZOL PRAIRIE DOG BAIT	08-Aug-2007	N	7173	LIPHAT.	.005

Final Questions and Answers for Topics for Rozol Prairie Dog Bait, EPA Reg. No. 7173-EIA (286) 1 Get Adm Rec for 7173-184; 2. Check OPPIN for reviews other than EFED and Efficacy; 3. Check E-Mails with company. Big Question: Are restrictions enough to mitigate against secondary poisoning?		
Topic	**Question**	**Answer**
I. Forms		
Application	Does app show container types/sizes	Plastic & Paper, need to clarify 1 to 2000 lb (app); 1 to 50 lb (label), need to clarify, try to limit to 4 lb Claims similarity to 7173-244; try to get co to remove
CSF	Is formula = to other prod?	Claims it is repack of 7173-184. Need CSF identical to 7173-184, consistent with technical %. May have already posed this question. Need to clarify. Block 17 = 1 lb, Needs to clarify.
Certification Form	Was it submitted/ acceptable?	
Form Exemption	Was one submitted acceptable?	
Data Matrix	Was one submitted and acceptable?	
II. Data		
Chemistry	Did we review data?	No. product identical to 7173-184. Co needs to cite chemistry data on 7173-184. Check matrix and note finding.
Acute Tox	Did we review data?	No. product identical to 7173-184. Co needs to cite chemistry data on 7173-184. Check matrix and note finding.
Occupat Risk Ass	Did we do an assessment?	No. [Double check OPPIN.] Use risk ass for 7173-242.

EFED	Did we do an assessment?	Yes. See review
HED	Did we do an assessment?	No. [Double check OPPIN.] Use risk ass for 7173-242.
Efficacy	Did we do an efficacy review?	Yes. See review. [Reminder: Do not mark originai.]
III. Label		
Chemistry	Are there any comments?	No. Follow label for 7173-184 and 242.
Acute Tox	Are there any comments?	No. Follow label for 7173-242.
Occup Risk Ass	Are there any comments?	No. Follow label for 7173-242 and revised PPE.
HED	Are there any comments?	No. Follow label for 7173-242 and revised PPE.
EFED	Are there any comments?	See review.
Efficacy	Are there any comments?	See review.
IV. Cond of Registr		
SLNs	What are SLN Nos. ?	CO—060009, KS-040003 (pen can), KS-070003); NE-060001; OK-080002 TX-070008, WY-060004 (pen can), WY-070005, check OPPIN for others
	Has Co agreed to canc SLNs	In 1-23-2008 cover ltr co claims that it will cancel the SLNs when EPA issues this registration. We need to get commitment from co, possible, and put those commitments in the Notice of Registration
New States	Will Co add new states only to this Prod?	Probably not but should try to secure agreement.

Dan Peacock, 16g, D:\4G Dan\Doc\Word\Chlorophacinone\7173-EIA, 286\Final Q and A for 7173-EIA, 286, 5-3-2009.doc

IRB EFFICACY REVIEW

PRODUCT NAME:	ROZOL PRAIRIE DOG BAIT
PRODUCT NO.:	7173-EIA
APPLICANT:	Liphatech, Inc. Milwaukee, WI 53209
DATE COMPLETED:	2/11/09
DP NUMBER:	350015
DECISION NUMBER:	389136
DATE OF SUBMISSION:	1/23/08 (received 1/30/08, sent for review 3/3/08)
ACTIVE INGREDIENT:	Chlorophacinone
FORMULATION:	0.005% a.i. grain bait
TYPE OF PRODUCT:	Rodenticide
PURPOSE:	Product registration: new use under §3 of FIFRA
DATA MRID NUMBERS:	473336-01, 473336-02, and 473336-03
GLP CLAIMED:	Yes
TEAM REVIEWER:	Daniel B. Peacock
EFFICACY REVIEWER:	William W. Jacobs, Ph. D.
SECONDARY REVIEWER:	John Hebert, Product Manager 7

3/18/09

BACKGROUND

This product is a 0.005% Chlorophacinone grain bait proposed for Federal registration as a "**RESTRICTED USE PESTICIDE**" for use only

> In underground applications to control black-tailed prairie dogs (*Cynomys ludovicianus*) on rangeland and noncrop areas in the states of Arizona, Colorado, Kansas, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, South Dakota, Texas and Wyoming.

The proposed label stipulates that "Bait must be applied at least 6 inches down prairie dog burrows" and directs would-be uses to

> Apply bait only between October 1 and March 15 of the following year, or before spring green-up of prairie grasses, whichever occurs later.

See efficacy reviews of 7/2/04 for KS-040004 and 1/9/08 for KS-070003. Those products were registered under §24(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for

special local needs (SLNs) in Kansas to control black-tailed prairie dogs.[1] The registration of KS-070003 was issued to supplant that of KS-040004, which was canceled on 10/14/08. SLN registrations for use of Chlorophacinone baits to control black-tailed prairie dogs have been issued in Colorado (CO-060009), Nebraska (NE-060001), Oklahoma (OK-080002), and Texas (TX-070008). In Wyoming, SLN registrations (WY-060004 and WY-070005) have been issued for Chlorophacinone bait products claimed to control "PRAIRIE DOGS (*Cynomys* spp.)".

The items routed for this efficacy review appear to be components of the original application to register this product. These items include:

- a letter dated "23 January , 2008" from Thomas Schmit, Liphatech's Manager of Regulatory Affairs, to John Hebert, Product Manager 7, Insecticide-Rodenticide Branch (IRB);
- a completed pesticide registration application form, **EPA Form 8570-1**, dated "23 January 2008" and signed by Schmit;
- an 8-page "**DATA MATRIX**" dated "23 Jan 2008" and signed by Schmit for "**Rozol Rodenticide Technical Powder**", EPA Reg. No. 7173-75;
- a "**TRANSMITTAL DOCUMENT**" dated "**23 January 2008**" and signed by Schmit;
- a black-and-white proposed label pin-punched "01•30•08"; and
- single copies two reports containing efficacy data.

A color copy of a proposed label that otherwise corresponds to the black-and-white version pin-punched "01•30•08" was added to in the efficacy review package. That item was attached to an e-mail note from Rachel Callies of Liphatech to Daniel Peacock of IRB.

The label proposed for this product would pertain to package sizes of "**1 pounds** [sic] **up to 50 lbs.**"

A copy of the ecological effects review of 7/27/06 pertaining to the Chlorophacinone SLN products NE-060001 and WY-060004 was made available to me shortly after I received the efficacy review package for 7173-EIA.

The "**DATA PACKAGE BEAN SHEET**" associated with the efficacy review package notes that the registrant is seeking to replace its existing §24(c) products claimed to control prairie dogs with 7173-EIA, which is proposed to be made available in more states than currently are covered by SLN registrations. Liphatech acknowledges as much in its application materials. According to information obtained through the website for the Smithsonian Institution's Natural History Museum, black-tailed prairie dogs occur in all 11 of the States listed on the label proposed for 7173-EIA. White-tailed prairie dogs (*C. leucurus*) and/or Gunnison prairie dogs (*C. gunnisoni*) also occur in several of the listed States.

DATA SUMMARY

Formulation

See confidential attachment to this review.

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[1] The label originally accepted for KS-040004 by the Kansas Department of Agriculture (KDA) claimed control of "**PRAIRIE DOGS (*Cynomys Sp.*)**". The label that KDA accepted for KS-070003 claims control of "**BLACK-TAILED PRAIRIE DOGS (*Cynomys ludovicianus*)**". The black-tailed prairie dog is the only prairie dog species that occurs in the wild in Kansas.

Efficacy Data

Yoder, C.A. (2008) Acute oral toxicity (LD_{50}) Chlorophacinone in black-tailed prairie dogs (*Cynomys ludovicianus*). Unpublished report, Project No. QA-1446, National Wildlife Research Center, U.S. Department of Agriculture, Fort Collins, CO, 86 pp.

MRID# 473336-01

Yoder conducted range-finding and formal LD_{50} studies using wild-caught black-tailed prairie dogs as subjects. Chlorophacinone in Propylene Glycol solutions was administered by oral gavage. For the range-finding study, 2 animals (1 male, 1 female) were dosed at each of the following levels: 0.25, 1, 2, and 4 mg Chlorophacinone per kg of body weight. For the formal LD_{50} study, 10 animals (5 males, 5 females) were given "targeted" dosages of each of the following levels: 0, 0.25, 0.6875, 1.125, 1.5625, and 2 mg/kg. The "nominal" dosages reportedly were 0.253, 0.6867, 1.127, 1.5600 and 2 mg/kg Chlorophacinone.

Yoder (2008) identifies the test material as "Rozol® Rodenticide Chlorophacinone technical" obtained from "LiphaTech, Inc.", which was reported to be 99.4% Chlorophacinone.

The prairie dogs used in this trial were trapped in Boulder County, CO. All were estimated to be one year or more in age when captured. The animals were ear-tagged and temporarily housed individually outdoors in Tomahawk live-traps. Depending on the specific model, the traps afforded the prairie dogs 2.25 or 3 ft^2 of bottom area. Prior to dosage, each prairie dog was moved indoors and placed in a cage with 4 ft^2 of floor area, with "a length of PVC pipe ... provided as a hide", and kept on a 12-hr/12-hr light/dark cycle at 60-70ºF. Subjects were weighed on days 0, 7, 14, and 21 during the test phase of the range-finding trial.

Animals were fed "grass hay or timothy hay cubes, apples, and carrots". The amounts of these feed items offered were adjusted during both studies based upon changes in subjects' weights and their apparent preferences. Yoder did not offer alfalfa cubes due to their reported high Vitamin K_1 content.[2]

Subjects "were fasted ≥ 17 hours" before dosing in the range-finding study. After gavage, the animals were checked "for signs of regurgitation or aspiration" and then returned to their cages, where they were observed 2X/day "for signs of chlorophacinone related toxicity, including pain and distress". After one animal died, the remaining animals were observed 3-4X/day. Personnel used weigh-back procedures to assess the amounts of apples and carrots that were consumed. Feed items dispersed by rodents from cages were not included in the weigh-back assessments. Corrections for moisture loss from feed were made.

The procedures followed for the formal LD_{50} trial were similar to those for the range-finding test except for the increase in the number of subjects used and the changes in dosage levels. The pre-gavage fasting interval was ≥17 hr. After dosing, subjects were observed 2X/day and then 2-3X/day after the first death was noted. Weigh-back and visual assessments of feed consumption were conducted during the formal LD_{50} trial. Adjustments to amounts of items offered were made based upon feedback from weighing subjects, which occurred on test days 0, 7, 14, and 22.

In both trials, animals found dead also were weighed; and

> Animals that were experiencing distress and appeared unlikely to recover were euthanized.

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[2] Vitamin K_1 is antidotal to anticoagulant rodenticides such as Chlorophacinone. In a "DEVIATION TO STUDY PROTOCOL" appended to her report, Yoder states that "Grass hay should more closely mimic the levels of Vitamin K1 prairie dogs are likely to be exposed to in the wild."

That approach would have shortened times to death for some subjects and might have inflated the number of animals classed as having been killed by Chlorophacinone.

Yoder (2008) reports that

> Two animals remained alive at the end of the [full LD_{50}] study despite having exhibited symptoms for approximately a week. One of these animals appeared to have been starting to recover. This underscores the need to balance obtaining scientifically valid data with animal welfare issues. During the range-finding test, three animals were euthanized compared to one animal in the LD_{50} test.

The assayed Chlorophacinone concentrations in the Polyethylene Glycol solutions used for oral gavage were close to but somewhat off (often on the high side) from the intended concentrations. If the results of these assays were available before dosing occurred in the LD_{50} test, the amounts of solutions gavaged to subjects could have been adjusted so that the targeted dosages were administered.

The fates of animal in the range-finding study are summarized in the table shown below.

DOSAGE (mg/kg)	NUMBER TREATED	NUMBER DEAD	DAYS TO DEATH
0.25	2	0	--
0.50	2	2	7, 14
1	2	1	11
2	2	2	12, 16
4	2	2	16, 18

These results were entered into SAS Institute programs for calculating LD_{50} values. A figure of 0.51 mg/kg reportedly was obtained.[3] Yoder's (2008) report does not indicate the sexes or weights of the individual subjects, nor does it note which 3 of the 7 animal deaths reported in this trial involved euthanasia.

The quickest reported time to death was one week. Four victims lasted 2 weeks or longer, and one or more of those reported deaths might have been hastened by test personnel. Although black-tailed prairie dogs appeared to be killed by a single oral administration of Chlorophacinone, their deaths were on the slow side, even for an anticoagulant.

Yoder (2008) reports that body weights decreased over time during the range-finding study. As a compensatory measure, the amount of carrots offered to the prairie dogs was increased from 95 g on day 0 to 100 g on day 7. The amount of apples offered was increased from 60 g on day 0 to 75 g on day 7 and to 100 g on day 14. Yoder ran moisture controls on some test days to assess weight loss from apples and carrots through evaporation. Consumption data are not given for individual animals.

Yoder presents consumption data for carrots and apples as mean "**g consumed/g body weight**" per day, which amounts to the percentage of body weight consumed daily. The means tended to increase or to be stable over time for the groups (0.25 and 1 mg/kg) that had one or more survivors and to decline near the times of death in groups that had no survivors. The highest

[3] The report's "**ABSTRACT**" gives a figure of 0.49 mg/kg.

daily mean reported for carrot consumption in the range-finding trial was 0.11 g/g, which works out to about to 95 g per animal per day. That figure is equal to all of the carrots offered to the group (1 mg/kg) for which 0.11 g/g consumption was reported on 4 of the first 6 post-gavage days.

Daily mean apple consumption increased over time in the groups that had survivors, as did the amount of apples made available. The reported mean daily apple consumption on day 0 was 0.06 g/g for 4 of the 5 dosage groups. The other group reportedly consumed 0.05 g/g on day 0. Based upon their reported day-0 mean body weights, the 5 groups consumed from ~54 g to >60 g of applies on day 0, which was all or nearly all of the amounts of apples that they were offered. The highest daily mean consumption figure reported for apples as any time during the range-finding study was 0.11 g/g for the survivor in the 1-mg/kg dosage group on days 20 and 21. As that animal's day-21 weight was 765 g, it would have consumed ~84 g of the 100 g of carrots made available to it then.

Yoder notes that the animals that survived the range-finding study "were hungry and ate immediately after food was placed in the cage." That observation and the apparent fact that survivors as well as victims lost weight over time suggest that subjects were fed insufficiently and perhaps inappropriately during the range-finding trial.

Yoder reports that animals that died during the range-finding test were more likely than survivors to shown overt signs of toxicosis. This information is presented in summary numbers within the text portion of the report and in bar graphs. The information is collapsed across subjects and observation days. Thus, the data do not show the time course to the expression of the various symptoms. The frequencies of adverse symptoms reportedly observed are summarized in the table shown below.

SYMPTOM	PERCENT OF OBSERVATIONS IN WHICH SEEN	
	Victims	Survivors
External Bleeding	48.2%	3.7%
Blood in Feces	19.4%	4.1%
Days without New Fecal Deposits	12.3%	<1%
Hunched Posture	15.1%	3.6%
Prostrate	4.1%	0.0%
Ocular Symptoms*	60.5%	~11%±
Cold to Touch	5.1%	0.4%
Shallow/Irregular Respiration	10%	~2%±
Unresponsive to Cage Entry	~41%±	~10%±
Did Not Move When Touched	24.0%	4.9%
In Comatose State	3.2%	0.0%

* Includes dull eyes, swollen eyes, closed or semi-closed eyes
± Figure estimated from a bar graph

Study personnel narrowed the dosage range used in the LD_{50} trial from the "1X, 2X, 4X, 8X, and 16X" scheme identified in the protocol to "1X, 2.75X, 4.5X, 6.25X, and 8X". According to an "AMENDMENT TO STUDY PROTOCOL" document appended to Yoder's (2008) report, this change was made because

Data from the range-finding test indicate the dose needs to be no higher than 2 mg/kg and no lower than 0.25 mg/kg.

Animal fates in the LD_{50} test are summarized in the table shown below.

DOSAGE (mg/kg)	NUMBER TREATED	NUMBER DEAD	DAYS TO DEATH
0	10	0	--
0.25	10	0	--
0.6875	10	0	--
1.125	10	5	10, 10, 11, 12, 12
1.5625	10	2	19, 20
2	10	6	9, 11, 13, 14, 14, 17

From these results, the SAS program calculated an LD_{50} value of 1.8 mg/kg, with the 95% confidence range being 1.35-5.29 mg/kg. The upper extreme of this range is >2½ times the highest dosage administered in LD_{50} trial. No deaths occurred before day 9 in this trial. Yoder's report does not indicate which one of the 13 victims was euthanized.

The results of the LD_{50} test call into question the decision to narrow the dosage range, which might have been influenced by premature euthanizing of subjects in the range-finding test.

Body weights decreased over the course of the LD_{50} trial, even for the 0-mg/kg (control) group. For the groups with no mortalities, mean animal weight dropped 19.4% for the control group, 17.3% for the 0.25-mg/kg group, and 20.2% for the 0.6875-mg/kg group. The 5 survivors in the 1.125-mg/kg group averaged 27.0% less in body weight than did the group's original 10 subjects on day 0. Over that same course of time, the mean animal weight dropped 11.5% for the 1.5625-mg/kg group (8 survivors) and 26.2% for the 2-mg/kg group (4 survivors). Although it is common for animals poisoned by anticoagulants to reduce food consumption and lose body weight prior to death, 2 of the experimental groups averaged a lower percent weight loss than did the control group which was gavaged with vehicle only. Consequently, something about the test circumstances was implicated in the animal's weight loss.[4]

At the start of the post-dosing period, each prairie dog was supplied, daily, 60 g of apples, 80 g of carrots, and a 25-g timothy hay cube for nourishment. The amount of apples given was raised to 80 g on day 10.

The highest mean daily "**g consumed/g body weight**" of carrots for any group in the LD_{50} test was 0.10 g/g by the 0.25-mg/kg group over the last 7 days of the trial, during which time that group's mean body weight dropped from 852.0 g to 725.0 g. From this weight range, I calculate that the daily consumption of carrots by the 0.25-mg/kg group animals was approximately 72-85 g/animal/day -- all or nearly all of the carrots that they were offered.

[4] Prairie dogs more readily consume grains during the latter half of the year than in springtime. This dietary change might be due in part to the curing of prairie grasses, but the seeds that they and other plants produce would be expected to contain more usable nutrients per unit of dry mass than would any of the items fed to captive blacktails in these Yoder's trials. The range-finding and full LD_{50} trials were conducted, respectively, in July and August of 2007.

The 0.25-mg/kg group also had the highest daily rate of consumption of apples by the end of the LD_{50} test. The mean daily "**g consumed/ g body weight**" figure for that group rose to a high of 0.10 on Day 15 and remained at that level for the remainder of the trial. As with the carrots, the 0.25-mg/lg group consumed essentially all of the apples that they were offered. On day 0, the mean rates of apple consumption were 0.5-0.7 g/g across groups. Those rates work out to ~50 g/subject/day for the control group, ~61 g/s/day for the 0.25-mg/kg group, ~56 g/s/day for the 0.6875-mg/kg and 1.5625-mg/kg groups, and ~57 g/s/day for the 2-mg/kg group.

For the LD_{50} test, Yoder (2008) reported symptoms in the manner that she did for the range-finding test (i.e., collapsed across groups, subjects, and observation days). The table below summarizes the reported symptoms.

SYMPTOM	PERCENT OF OBSERVATIONS IN WHICH SEEN	
	Victims	Survivors
External Bleeding	26.9%	8.2%
Blood in Feces	9.5%	3.6%
Days without New Fecal Deposits	8.1%	2.3%
Hunched Posture	8.1%	1.8%
Prostrate	~5%±	~1%±
Ocular Symptoms*	23.2%	~6%±
Cold to Touch	5.1%	0.4%
Shallow/Irregular Respiration	3.1%	~1%±
Unresponsive to Cage Entry	14.4%	5.2%
Did Not Move When Touched	12.8%	2.0%
In Comatose State	~3%±	~1%±

* Includes dull eyes, swollen eyes, closed or semi-closed eyes
± Figure estimated from a bar graph

Most of the subjects that exhibited external bleeding bled from only one site. One victim bled from 5 sites. No survivor showed external bleeding from more than 2 sites.

The absences of data on individual subjects, time-course data, and raw data in general greatly limit the depth of review that the Yoder (2008) report can be given and also limit the inferences that can be drawn from it. It seems clear enough that single orally administered dosages of Chlorophacinone at dosages from approximately 0.5 to 2 mg/kg of body weight will kill some but not all black-tailed prairie dogs receiving them. Times to death were slow. That deaths occurred more than 2 weeks after a single administration suggests that Chlorophacinone remains in the body and pharmacologically active for 20 days or more. Nutritional issues sufficient to cause weight loss in non-poisoned animals might have contributed to some of the observed deaths. Most victims reportedly were symptomatic prior to their deaths.

Lee, C.D. and Hyngstrom, S. E. (2007) Field efficacy and hazards of Rozol bait for controlling black-tailed prairie dogs. Unpublished report, Liphatech, Inc., Milwaukee, WI, 300 pp.

MRID# 473336-02

This report previously was assigned MRID# 472677-01 and was considered in the efficacy review of 1/9/08 for KS-070003. Those discussions were imported into and edited for this review.

Lee of Kansas State University (Manhattan) and Hyngstrom of the University of Nebraska (Lincoln) directed the research described in this report for Liphatech. Schmit served as quality assurance officer for this project. The field phase of the study began in the autumn of 2006 and concluded in the spring of 2007.

The test substance used was described as "Rozol Pocket Gopher Bait, EPA Reg. No. 7173-184" which was reported to have SLN registrations in KS and NE. Bait lots #284061 and #19906 reportedly were used in this trial. According to a "**CERTIFICATE OF ANALYSIS**" sheet signed by Melissa Zobel on 10/12/06, lot #284061 was manufactured on 10/11/06 and, on the same day, assayed at "59.13 mg/kg" (0.005913%) Chlorophacinone. A "**CERTIFICATE OF ANALYSIS**" sheet signed by Shane Nimmer on 1/4/07 indicates that lot #19906 was manufactured on 7/18/06 and was assayed as being "53.54 mg/kg" (0.005354%) Chlorophacinone on 1/4/07. Protocol information appended to the main report indicates that the researchers intended to use a single lot of bait for this project. Bait from the older lot was used after the intended lot was depleted.

The efficacy report does not include formulation sheets for the 2 bait batches. Such documents should be obtained from Liphatech and reviewed before a final decision on the §3 registration application for 7173-EIA is rendered to verify the composition of the test material used in this trial.

The stated objectives of this research project were as quoted below.

> 1. Determine the efficacy of Rozol Prairie Dog Bait in controlling black-tailed prairie dogs, when applied in-burrow, at the rate of ¼ cup of bait per active burrow;
>
> 2. Determine the (approximate) number of prairie dogs that are available after death to predators/scavengers on the surface of the ground;
>
> 3. Determine the amount of granules of Rozol Prairie Dog Bait that are moved to the ground surface, out of the burrows, by the normal activity of prairie dogs, predators and scavengers or prairie dogs, or by other wildlife, livestock or domestic animals;
>
> 4. Provide carcasses of black-tailed prairie dogs collected from treated areas, for tissue analysis to determine whole-body and liver concentrations of chlorophacinone residue;
>
> 5. Determine if the time of year when application is made has measurable influence on the efficacy, availability of carcasses on the surface of the ground, and/or the tissue concentrations of chlorophacinone residue.

Animals that die within burrows will be available to certain types of predators and scavengers (e.g. mustelids) that are active during winter and to such organisms as well as to snakes and burrowing owls at other times of the year.

In the course of this research, efficacy evaluations were made in October and November of 2006 – "early season application (fall)" – November and December of 2006 – "mid-season application (early winter)" – and March and April of 2007 – "late season application (late winter)". In this review, the time periods are referenced by month. Doing so more accurately places them in time than do the seasonal descriptive terms coined by the authors. Two of the bait applications for this study were made in autumn (on 10/20/06 and 12/2/06). The third application, on 3/9/07, was in winter.

Tests were run at a total of 13 sites located in Kansas and Nebraska. Within seasonal trials, study areas were geographically relatively close to one another. A monitored untreated control

(check) site was included in the design for each of the seasonal trials. Two test plots were baited in October of 2006. Four plots were baited in December of 2006; and 4 more were baited in March of 2007. Information on locations, areas, and treatment groups for study sites is summarized in Table 1.

Two indices for evaluating prairie dogs activity were used before and after bait applications: visual counts and closed burrows. These methods often are employed in field efficacy trials involving prairie dogs or ground squirrels. The 2 methods were to be run sequentially according to protocol appended to the research report, but entries on raw data sheets indicate that they often overlapped in time. These methods typically are not run concurrently. Closing burrows and the human activity associated therewith might affect the number of prairie dogs visible above ground.

As it is typically performed in field efficacy trials, the visual counts method entails 3 scans conducted on each monitored plot over the same time period each day (within plots) for 3 consecutive days. The highest number of target species animals seen during the 9 scans is taken as the index for the census period. For this trial, 2 scans were taken on the morning and 2 more in the afternoon of one or two days (Table 1). The highest number of prairie dogs seen in any one scan became the index figure for that plot (Table 2). After the visual counts scans were completed, burrows were to be plugged with earth for the start of closed-burrows assessments. However, scans for the visual counts method sometimes were conducted between the times when burrows were closed and re-checked (see Table 1).

For the closed burrows method, the typical procedure is to close some or all of the seemingly active burrow openings within the census area, mark the closed burrows with flagging, and re-examine them subsequently for signs consistent with opening by targeted rodents. The usual interval between when burrows are plugged and when they are reopened is 48 hours, but re-checking after 24 hours sometimes is practiced. Lee and Hyngstrom (2007) re-checked burrows after 24 hours. According to the protocol for this study, burrows were to be considered as active only if evidence found upon re-inspection was consistent with their having been opened by prairie dogs (as opposed to a "non-target animal"). As noted in Table 3, some burrows on at least one plot apparently were judged to have been opened by "*rodents*" other than prairie dogs.

On each study plot, 100 seemingly active burrows were to be plugged and marked with turf paint. These burrows were to be on 2 transect lines of 50 burrows each. Transect lines were intended to cross and to be "approximately perpendicular" to one another. If the colony size, shape, and burrow density did not permit two crossing lines of 50 active burrows each, procedures were to be adapted to get to 50 burrows using other systematic means. In the end, the researchers decreased the number of seemingly active burrows plugged and marked to 50 (2 crossing transects of 25 burrows each) for "the smallest colonies" involved in these trials. As can be seen from Table 3, there were 3 such "smallest" colonies in the March-April trial and none in the earlier trials. All plots had two transect lines established for assessing burrow activity. "Plot Diagrams" presented in "Appendix 3" to the Lee and Hyngstrom (2007) report suggest that one or more of the transect lines used to assess efficacy extended virtually to at least one edge of many of the study plots. Additional transects were established on baited plots to assess bait availability and to search for carcasses. Transects for carcass searches extended beyond the edges of the plots.

In this study, the 2 census methods often overlapped temporally, with the total period of time elapsing from their initiation to their completion being 2 or 3 days (Table 1). Short census periods notwithstanding, the researchers used a number of interesting methods of data analysis. Some of these involved indices for grain removal and relocation which employed conversions of continuous-variable data into what essentially amounted to ranks.

Each bait application

> was made by qualified applicator, who holds the appropriate license for state where the study plots were located.

The authors state that ¼ cup of bait was deposited into each active burrow and that sufficient

> Care was taken to place the bait at least 6 inches into the burrow, and no bait was left on the surface of the ground. Any bait that was spilled above ground or placed less than 6 inches down the burrow was removed before proceeding to the next burrow. A count of the number of burrows treated was maintained and recorded by the investigator(s) making the bait application. Bait application was made by hand, or with a dispensing device mounted on an all-terrain vehicle.

The ¼-cup amounts of bait were measured in kitchen-type measuring cups. Apparently, different cups were used at different sites. Cups were not calibrated as to exact capacity but were "used in a consistent manner when placing bait in prairie dog burrows".[5] Lee and Hyngstrom (2007) state that there were "approximately 1650 grains" in each ¼ cup of bait.

According to protocol information in "Appendix D" to the protocol ("in Appendix 4" to the main report),

> Any bait dispensing device used must be calibrated to ensure that it dispenses the correct amount, with minimal variation between "doses" dispensed by the machine. The performance of the machine will be documented by calibration prior to the first use on any day, and at the conclusion of baiting at the end of the work day, following any damage, repair or adjustment made to the device, and following the transportation of the device to another site, according to the following procedure ... [not quoted here].

Calibrations of the "*Prairie Dog Feeder*" equipment used on many of the treated plots in the Lee and Hyngstrom (2007) trial ran in the ~47- to 53-g range (roughly 1.6-1.9 oz). There was close agreement in "dose" weights within runs of 10 calibration checks; but runs conducted on the same day, perhaps with different equipment, could be a few grams apart in central tendency and varied between applicators. The proposed label for 7173-EIA directs that "¼ cup (53 grams or nearly 2 ounces)" of bait be applied "at least 6 inches down active prairie dog burrows." The 53-g (~1.9 oz) amount exceeds the average amount of bait delivered in every calibration trial for the "*Prairie Dog Feeder*" and the expected weight of ¼ cup of the test bait. To maximize chances for effective treatment and to make operational use as consistent as possible with what went down holes in the Lee and Hyngstrom (2007) field trial, the label should direct use of a bit more than ¼ cup of bait per hole. Calling for a "heaping ¼ cup" might get the amount right but almost certainly would increase the likelihood of bait being spilled on the surface. Calling for "a shallow ⅓ cup of bait" might get the mass of bait used per hole closer to what went down in the field trial and reduce the incidence of spillage as well.

Based upon information supplied by the registrant, ⅓ cup of the 7173-184 product should weigh about 2.1 oz (60 g). However, Liphatech did not alter the bulk density figure claimed for 7173-184 when that product's formulation was amended in 2005. If the density figure provided by Liphatech for 7173-184 is incorrect, my calculations regarding the weights of ¼ and ⅓ cup of that bait would be inaccurate.

Bait reportedly was applied to entire prairie dog towns. Each town was treated once. These towns were 2.1-41.5 acres in area and were isolated from one another by "roadways, other

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[5] From information supplied for 7173-184, I calculate for the efficacy review of 1/9/08 for KS-070003 that ¼ cup of bait should have weighed about 1.6 oz (45.3 g). A single round of treatment at the rate of ¼ cup/burrow opening would provide more or less than that amount of bait per prairie dog depending upon whether the number of openings was greater or less than the number of live prairie dogs.

natural or artificial barriers, or large areas of land not occupied by prairie dogs." There apparently were no treated buffer zones, as such, surrounding census areas. However, areas adjacent to census plots apparently were treated at two sites (see notes to Table 1). Each town reportedly "contained at least 20 individual animals."

"Bait Availability on the Ground Surface" was assessed over the first 7 days of bait exposure. The study plan called for a transect of 50 burrows per colony to be established for this index and for inspectors to assess how much bait was found on the ground surface and how much was greater or less than 6 inches down the hole.

Following treatments, personnel reportedly engaged in systematic carcass searches within plots and extending ~100 feet beyond their borders "in all directions". Eight to 11 searches were performed on each of the treated plots. Searches

> were conducted during afternoon hours (weather permitting) to minimize the availability of carcasses to nocturnal predators/scavengers.

Such a procedure likely would not routinely be followed during operational use of a product such as 7173-EIA.[6] The label proposed for this product requires 2 post-treatment visits to baited plots. The first visit is to occur

> within 5 to 10 days after bait application, to collect and properly dispose of any bait or dead or dying prairie dogs that may have come to the surface. A second carcass search and collection must be made 14 to 21 days after bait application.

The protocol for the Lee and Hyngstrom (2007) trials called for "one recovered prairie dog carcass" from each poisoned plot to be collected and frozen for subsequent residue analyses.

The authors note that weather conditions affected when some study procedures were conducted. The period of time elapsing between bait applications and the conclusion of census activities and carcass searches varied from season to season, being 22 days for the October-November trials, 26 days for the November-December trials, and 23 days for the March-April trials.

At one site, the land owner

> Treated and covered all active burrows prior to the final plugged burrow count and visual observation.

Those activities corrupted the post-treatment activity assessments for that site. The visual counts method was used (with questionable results), but the closed-burrows method was not attempted. The copies of raw data sheets appended to the main report include the notation that, at that site,

> *Landowner plugged all burrows yesterday "so they would not move back in." He said he saw no pdogs but some digging since the rain. Used exploder on 4-1-07 am!*

Use of a burrow-exploding device on 4/1/07 preceded the afternoon visual counts survey conducted that afternoon and the morning visual counts survey conducted on 4/2/07. One prairie dog reportedly was seen on the plot on during each of the 4 scans conducted on those days

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[6] A primary objection to using Zinc Phosphide to control prairie dogs is the need to prebait colonies with untreated grain corresponding to that used in the toxic bait before the latter is applied. It seems unlikely that individuals reluctant to prebait would readily make repeated visits to baited sites to search for and remove or bury animal carcasses.

(Table 2). Thus, sequential use of the bait and the device did not eliminate prairie dog activity at that site.

The efficacy estimates obtained via the visual counts and closed-burrows methods are summarized in Tables 2 and 3, respectively. For treatment periods in which there was a decline in the relevant index on the untreated plot, the estimate of the effects of treatment on the index has been adjusted downward accordingly in those Tables.[7] On all treated plots, post-treatment activity as measured by either index was much lower than during the pretreatment census period. Where applicable, adjustments for results from check plots altered the estimates from poisoned plots very little.

Due to the temporal overlapping of the two census methods, it is possible that deliberately closing burrows would have reduced the number of prairie dogs visible above ground. In treated plots, the number of burrow openings plugged to census activity was a minority, often a small minority, of those that were treated. Therefore, the effects of human-closed burrows on the number of places from which prairie dogs could make themselves visible could have been relatively slight. It is not clear whether and to what degree the recent human presence and shoveling activities on the plots affected the willingness of blacktails to show themselves while humans were observing the plots.

Raw and adjusted post-treatment reductions in activity indices greatly exceeded the 70% (minimum) activity reduction criterion set forth in our guidelines for field efficacy studies of lethal rodenticides. The effects of overlapping of census methods on activity indices probably were small, especially where 25% or less of the burrows at the site were plugged during the visual counts scans. Therefore, it seems unlikely that the data were confounded to such an extent that actual effects of treatment that were less than 70% were made to appear to be much greater. It seems, then, that satisfactory levels of control of black-tailed prairie dogs were achieved on all treated plots, except for the Magnani site in the March-April trial where the landowner's behavior confounded all estimates of efficacy.

That such levels of control could be obtained through placing <2 oz of bait in each burrow opening seems puzzling, especially considering the body size of adult blacktails. There likely would be enough Chlorophacinone present from 1.6- to 1.9-oz placements to control all prairie dogs present if they shared the bait relatively equally and did not consume it all at one feeding. Anticoagulants are slow-acting compounds that do not affect rodents' behavior and food consumption very much (except perhaps for their foraging strategies) over the first 2-4 days after feeding begins, after which time animals that have ingested sufficient amounts of the poison weaken and die.

The minimum single-point placement amount for controlling commensal rats with anticoagulant baits is set at 4-oz (or the rough equivalent in numbers of placepacks or bait blocks). Although the density of placements in prairie dog burrow openings may exceed that realized in the 15- to 30-foot spacing of placements when commensal rodents are targeted, adult blacktails are $\geq$2 times the size of adult Norway rats. It may be that blacktails are extremely sensitive to Chlorophacinone at all times or over winter, when stresses from lower temperatures might enhance the effects of anticoagulants.

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[7] Lee and Hyngstrom (2008) adjusted control estimates in instances when there was a "post-treatment" increase in activity on the relevant untreated plot. Such adjustments are based on assumptions that there would have been similar increases on the poisoned plots but for the use of the bait. The traditional and more conservative approach is to regard negative "post-treatment" effects on check plots as suggesting that other factors (e.g., seasonal effects, "natural" mortality at a time of year with no reproductive recruitment, etc.) might have acted to reduce activity independent of use of the bait. When activity indices increase on check plots after the time of treatment, the conservative assumption is that the effects of any negative influences other than baiting on the activity of the targeted species are unlikely to have been significant. Consequently, activity assessments from treated plots are not adjusted.

Lee and Hyngstrom (2007) report that "Bait was available in and around burrows on all colonies up to 7 days after treatment", with "all colonies" presumably meaning "all treated colonies". As would be expected, the amount of bait visible within and near burrows declined over time following application. The green dye on the bait should have facilitated its detection.

Researchers assessed all treated sites for amounts of visible bait and the depths at which it was observed varied among treated colonies (Tables 4a, 4b, 4c, 5a, 5b, and 5c). Some bait was observed on the surface on at least one occasion following application during each of the baiting periods, although surface bait reportedly was seen on only one day and in only one of the four colonies that were treated in March of 2007. On 2 of the 10 towns that were baited, across treatment seasons, there reportedly was no bait observed 7 days following application in or around any of the 50 burrow openings that were evaluated for bait availability. For the other 8 towns, the percent of burrows with visible bait a week after treatment ranged from 2% to 24%. The 2 towns with the highest amount of burrows showing some evidence of bait after a week were the Kansas towns involved in the December baiting. In those 2 towns and in all colonies involved in the March baiting, the most common depth at which bait reportedly was observed was 0-6 inches.[8]

Bait observed ≥6 inches down a hole would be at a depth consistent with proper application, whereas bait closer to the surface or on it either would have been applied inaccurately or moved upward by non-human agents such as prairie dogs, other animals, or air currents. Lee and Hyngstrom (2007) used a rating system for amounts of bait found on the surface and at depths of 0-6 inches or >6 inches. Numbers in the range of <25 grains observed at specified depth ranges were assigned the "Grain Index" number of "13" (i.e., the median of the numbers between 0 and 25). Similarly, counts or estimates of 25-100 grains were given an index of "63". Observations of >100 grains were assigned the seemingly arbitrary score of "113" (perhaps to maintain an interval of 50 between successive scores). Lee and Hyngstrom calculated overall Grain Index figures by summing the occurrences of results in each of these 3 ranges.

Tables 5a, 5b, and 5c to this review present the occurrences of bait observations at the depths and amount ranges that are indicated on raw data sheets appended to the Lee and Hyngstrom (2007) report. Across treated towns, reported observations of bait on the surface were most commonly in the <25 grains range, with the only instances of more than 25 grains being observed on the surface occurring within 3 days of application. Apparently, one or more types of agents tended to relocate and/or consume grains that had gotten to the surface. Numbers of grains ≥25 were more commonly reported where bait was seen within burrows at depths of 0-6 inches or >6 inches. At such depths, the presence of bait and the numbers of grains observed declined over time, again suggesting relocation and/or consumption.

The two different methods of putting bait into burrows – hand (measuring cup) and mechanical – used in this study might have affected the tendency for bait to be seen on the surface and/or at depths <6 inches. Table 6 sorts the 10 treated sites according to whether they were treated by hand only, by "*Prairie Dog Feeder*", or by a combination of those 2 methods. Only the observations made one day after treatment are considered in Table 6 as the Day-1 observations were the recorded ones made closest to the time of treatment. Table 6 shows clearly that, regardless of the method(s) used to treat burrows, only a small percent (0-6%) of holes had visible bait on the ground surface surrounding them. That 30-72% of holes had no bait visible in or around them a day after treatment seems to mean that some agent(s) consumed, removed, or otherwise concealed the particles. The proportion of holes with no bait seen on Day 1 in positions inconsistent with the requirement to place bait at depths ≥6 inches, varied from 50% to

[8] The raw data sheets indicate only one depth at which bait was observed for each burrow for each day of observation. That circumstance probably means that the observations were scored according to the shallowest depth at which bait was observed and, therefore, that a report of bait being observed on the surface probably did not mean that there was no bait observed in the hole.

98% among assessed burrows on the 10 poisoned plots. The 3 plots with the fewest observed holes showing bait less than 6 inches down them were among the 4 that were treated strictly by hand. However, the fourth plot (Wiese West) that was hand-baited had visible bait 0-6 inches deep, one day after treatment, in nearly half of the observed burrows.

First-generation anticoagulants such Chlorophacinone tend to be much more toxic on a mg-poison/kg-body-weight basis when consumed in small amounts over several days rather than when the same amount is eaten on one day (e.g., Ashton, *et al*, 1987). That there was some bait remaining over several days of treatment would have made it possible for the bait to poison prairie dogs more efficiently than might have been the case had all bait been eaten on the first day. However, what happened to the baits that were not observed can only be inferred from other evidence. From the post-treatment declines in indices prairie to dog activity, including fewer live blacktails being seen, it seems highly likely that much of the missing bait was consumed by the target species.

Lee and Hyngstrom (2007) report that the 10 animal carcasses found above ground across the 10 poisoned towns included 9 prairie dogs. The earliest carcass findings were made 10 days post application. The last was made 25 days after bait was applied. Eight of the 10 carcasses were "completely intact", but the other 2 "had been scavenged." Prairie dog carcasses were found at a rate of 1 per 14 acres searched (0.07 carcasses/acre). Results of residue analyses of usable carcasses are reported in the Primus (2007) paper discussed below. The authors also report having seen "5 impaired prairie dogs" $\geq$10 days after bait applications.

A dead eastern cottontail rabbit (*Sylvilagus cuniculus*) also was found following treatment.

Lee and Hyngstrom (2007) report having observed the following types of vertebrate organisms "in and around the perimeter of all sites" that might have shown interest in consuming the grain bait: meadowlarks (*Sturnella* spp.), horned larks (*Eremophila alpestris*), mourning doves (*Zenaida macroura*), rock doves (a.k.a. "pigeons", *Columba livia*), and eastern cottontails. Also observed at study sites were the following carnivorous types: killdeer (*Charadrius vociferus*), great blue herons (*Ardea herodias*), red-tailed hawks (*Buteo jamaciensis*), rough-legged hawks (*Buteo lagopus*), northern harriers (*Circus cyaneus*), and coyotes (*Canis latrans*). Except possibly for killdeer, all of these species would be expected to show some interest in hunting live prairie dogs and/or in feeding upon their carcasses.

Attempts at monitoring the effects of Chlorophacinone baiting on nontarget species in this study apparently were limited to the aforementioned carcass searches. Although those searches were numerous and covered several weeks following bait application, the efforts reportedly did not extend more than "about 100 feet in all directions" beyond the perimeters of the treated towns. Anticoagulants kill very slowly. Therefore, it seems reasonably likely that wide-ranging species such as volant birds and coyotes could have been well off site if and when they succumbed to primary and/or secondary exposure to Chlorophacinone.

Pretreatment capture and radio-equipping of nontarget species really is needed to determine reliably whether and where specific individual animals expire following treatment. Necropsies and residue analyses can be performed on carcasses to assess whether exposure to the anticoagulant occurred and, perhaps, whether the anticoagulant was the likely cause of death. However, if Chlorophacinone were being used by others within the study area, its implication in the deaths of any nontarget animal would not necessarily mean that the exposure resulted from any specific use or use pattern. The KS-040004 product, for one, likely would have been available in the vicinities of the Kansas sites involved in this field trial. One or more anticoagulant products likely would have been available for use near the Nebraska sites (e.g., NE-060001).

As noted above, 0-6% of observed burrows had bait exposed on the ground surface one day after treatment, and there was some evidence of surface bait visible as late as a week post-treatment (Tables 4a, 4b, 4c, 5a, 5b, 5c, and 6). Bait less than 6 inches deep, including surface bait, was

observed at all treated sites on 5-7 of the days covering the first week following bait application. Bait less than 6 inches deep could be reached by many types of animals, including livestock.

In light of such information, the proposed label's 3-day post-treatment grazing restriction seems inadequate. The incidence of surface bait may seem relatively low on a percent basis, but it must be remembered that hundreds or thousands of holes variously were baited on the poisoned plots involved in the Lee and Hyngstrom (2007) study. If the 6% incidence of surface bait one day following application reported at the Hogan site held for all 3088 burrows treated there, there would have been surface bait at ~185 burrows in that prairie dog town one day after treatment and at about ⅓ that many on 4 of the 6 subsequently monitored days. If the incidence of surface bait and/or bait <6 inches deep at all of the 1787 treated holes at the Ryan South occurred at the same rate as was observed at the 50 burrows sampled, ~786 (44%) of those holes would have had bait potentially accessible to livestock a day after treatment. Three days after treatment, when the label authorizes grazing, the 50% proportion of holes with bait at depths of <6 inches would have meant that ~894 holes might have had livestock-accessible bait. A week after treatment, ~286 holes on Ryan South might still have had livestock-accessible bait.

Post-treatment monitoring of livestock-available bait presence was not continued until an asymptote was approached, although incidences were much lower a week following treatment than they were one day after application. It seems clear enough that 3 days or a week of post-treatment grazing restrictions would not be sufficient to assure the public of safe beef (or milk, should dairy cattle be grazed on treated sites). Residue chemistry issues aside, looking at bait presence alone suggests that at least a one-month restriction should be imposed, to err on the side of safety (presumably).

Primus, T.M. (2007) Determination of Chlorophacinone residues in prairie dog whole body and liver tissues. Unpublished report, Project No. QA-1405, National Wildlife Research Center, U.S. Department of Agriculture, Fort Collins, CO, 58 pp.

MRID# 473336-03

Primus (2007) reports on 2 series of assays of carcasses for Chlorophacinone residues, the second of which pertains to animals collected in the Lee and Hyngstrom (2007) study.

The first series involved a sample of 12 prairie dog carcasses. Of those, 8 were judged to be "in acceptable condition for analysis". The other 4

> were desiccated or eviscerated to the point that insufficient tissue was available or unacceptable for analysis.

At least 7 of the 8 assayed carcasses apparently were collected from a site treated with Chlorophacinone on 3/14/06. The other carcass was of an animal "Found Dead East Pasture 3/30/06". The assays were conducted on 9/6/06. The laboratory report on their results is dated "10/13/06".

In whole-body assays of the carcasses collected in 2006, Chlorophacinone was detected in each animal. Concentrations ranged from 0.849 to 2.24 ppm (limit of detection = 0.054 ppm). All liver tissue samples from those animals also tested positive for Chlorophacinone (3.28-8.31 ppm, limit of detection = 0.035 ppm). Combining residue results with adjustments for the livers' being 2.6-4.8% of total carcass weight led to calculated total carcass residue levels of 1.11-2.37 ppm.

The second laboratory report pertained to carcasses of 9 prairie dogs and 1 cottontail rabbit. Those carcasses were assayed during May of 2007. The sites and dates of collection reported for these carcasses are consistent with their having have been those collected during the Lee and Hyngstrom (2007) trials. One of the prairie dogs carcasses "was desiccated and eviscerated" such that it could not be assayed.

The 8 prairie dog carcasses assayed had whole-body residues of 0.090-1.25 ppm Chlorophacinone (limit of detection = 0.083 ppm). Liver residues in these same animals were 0.524-4.93 ppm Chlorophacinone (limit of detection = 0065 ppm). Calculated total carcass loads for these animals were 0.113-1.35 ppm.

Chlorophacinone residues in the cottontail were 0.094 ppm for whole-body and 0.448 ppm in liver for a calculated total carcass load of 0.107 ppm.

These data are consistent with the animals' having been exposed to and poisoned by Chlorophacinone. That the residues in liver were higher than in whole-body-minus-liver is consistent with findings previously reported for anticoagulant rodenticides in various species. The 100% incidence of residues among the tissues assayed indicates that predators and scavengers feeding on carcasses available due to use of Chlorophacinone bait would be exposed secondarily to the anticoagulant.

LABEL

From the standpoint of efficacy, the label proposed for 7173-EIA needs only a few changes.

The proposed "**Use restrictions:**" subsection of the "**DIRECTIONS FOR USE**" would limit use of the product to below-ground applications to control black-tailed prairie dogs in 10 states (see quoted text at the beginning of the BACKGROUND section of this review). The bait is to be applied "at least 6 inches down prairie dog burrows". The application season is to be from 10/1 of one year until 3/15 of the next "or before spring green-up of prairie grasses, whichever occurs later." As I understand them, the seasonal limitations on use of anticoagulant baits for prairie dog control are intended to protect some types of migratory raptorial birds. The migration patterns of such species might be affected by weather but probably would not be affected directly by "spring green-up". Bait acceptance may be reduced by "spring green-up", however, due to prairie dogs' preference for new- and renewed-growth vegetation. Prairie dogs' willingness to accept grain-based bait increases when the grass cures (yellows) in the late spring or in summer, well before October 1.

The "**Application:**" paragraph calls for "1/4 cup (53 grams or nearly 2 ounces)" of bait to be used per treated burrow and emphasizes the sentence "**Make sure no bait is left on the soil surface at the time of application.**" In light of the findings on bait depth reported by Lee and Hyngstrom (2007), the label should make it clearer than it does now what is meant by "at least 6 inches". As prairie dogs and other animals that occur in prairie dog towns seem to occasionally move bait to the surface or to locations within burrows that are <6 inches deep, it might be difficult to enforce against marginal misuse (i.e., occasional spillage of bait on surface or not getting the entire placement to the required depth). Whole 2-oz placements made on the surface or just inside burrow openings likely would be conspicuous due to the amount of dyed bait involved, especially if sites were inspected shortly after treatment.

If carcasses are to be buried on-site, they must be placed "in holes dug at least 18 inches deep, or in inactive burrows." Although burying carcasses is to include "covering and packing the hole or burrow with soil", those measures seem unlikely to thwart all semifossorial predators and scavengers (e.g., badgers). The expression "inactive burrows" should be expanded so that it is clear that it means burrows apparently not being used by prairie dogs or any other animals that are potentially vulnerable to secondary poisoning by Chlorophacinone.

CONCLUSIONS

1. The results of the acute oral toxicity study reported by Yoder (2008; MRID No. 473336-01) suggest that the acute oral LD of Chlorophacinone for black-tailed prairie dogs is 1.8 mg/kg of body weight, with a 95% confidence interval 1.36-5.44 mg/kg. These data might overstate

the animal's sensitivity to the anticoagulant somewhat as the test facility had difficulty maintaining the control-group subjects at their initial body weights. The possibly premature euthanizing of 3 of the 7 reported deaths in the range-finding study may have led to the use of too narrow a dosage range in the LD_{50} study.

2. The efficacy report by Lee and Hyngstrom (2007; MRID No. 473336-02) suggests that single applications of ¼ cup of bait effectively controlled black-tailed prairie dogs under the conditions of use. The census methods involved in the study overlapped in time and were conducted for shorter periods of time than is typical for field efficacy trials of rodenticides on farm and rangelands. However, the trials were adequate to support the fundamental label claim.

   Information on equipment calibration suggests that the amounts of bait dispensed by the "*Prairie Dog Feeders*" usually were 47-52+ grams but seldom reached "53 g or nearly 2 ounces" per burrow. Such amounts would seem to exceed the weight (1.6 oz) of a level ¼ cup of bait, if previously reported data on product density are accurate.

3. Residue data reported by Primus (2007; MRID No. 473336-03) indicate that all 8 black-tailed prairie dog carcasses and a cottontail rabbit carcass collected during the Lee and Hyngstrom (2007) project tested positive for Chlorophacinone in assays of liver tissue and in whole-body (minus liver). Similar results were obtained with 8 black-tailed prairie dog carcasses collected during an earlier project.

4. The comments listed below pertain to the "**DIRECTIONS FOR USE**" section of the "(02308)" proposed label for 7173-EIA.

   a. Change the second sentence of the "**Use Restrictions:**" paragraph so that it reads:

      Bait must be applied at least 6 inches down prairie dog burrows (measured from the farthest back portion of the burrow opening).

   b. Retain the proposed per-burrow application amount in the "**Application:**" paragraph if the weight of a level ¼ cup of formulated bait averages 53 g. If not, adjust the gram- and ounce-equivalents on the label to be consistent with a level ¼ cup of this product. Weigh at least 10 level ¼ cups of bait to make the weight determination. (Lee and Hyngstrom (2007) report having used volume measures to determine how much bait to use.)

   c. In the fifth (next-to-last) sentence of the "**Follow-up:**" paragraph, change "inactive burrows" to

      inactive burrows (no longer being used by prairie dogs and not used by other species).

REFERENCE

Ashton, A.D., Jackson, W.B., and Peters, H. (1987) Comparative evaluations of LD_{50} values for various anticoagulant rodenticides. In: Richards, C.G.L. and Ku, T.Y. (eds.) Control of Mammal Pests. Taylor & Francis, London, New York, Philadelphia, 187-197.

Table 1. Sites and schedules used in 2006-2007 field efficacy trial for Rozol bait (Lee and Hyngstrom, 2007; MRID# 473336-02).

Site Name	General Location	Acreage	Treatment	Pretreatment Visual Counts Date(s)[AM-PM]	Post-treatment Visual Counts Date(s) [AM-PM]	Pretreatment Closed-Burrows Dates	Post-treatment Closed-Burrows Dates	Date Baited	Burrows Treated	Bait Buckets Used
TNC Control	Great Bend, KS	23.3	None	10/19/06	11/10-11/06	10/19-20/06	11/10-11/06	-	-	-
Sallee	Great Bend, KS	30.7	Rozol	10/19-18/06	11/10-9/06	10/18-19-06	11/9-10/06	10/20/06	2680	10
Hogan	Great Bend, KS	41.5	Rozol	10/19-18/06	11/10-9/06	10/18-19/06	11/9-10/06	10/20/06	3088	12.66
Ryan Control	Atwood, KS	3.8	None	12/1;11/30/06	12/27-28/06	11/30-12/1/06	12/27-28/06	-	-	-
Ryan South	Atwood, KS	24.4	Rozol	12/1;11/30/06	12/27/06	11/30-12/1/06	12/27-28/06	12/2/06	1787	?
Ryan Cemetery	Atwood, KS	14.5	Rozol	12/1;11/30/06	12/27/06	11/30-12/1/06	12/27-28/06	12/2/06	1503	?
NE East Lashley	Trenton, NE	3.8	Rozol	12/1;11/30/06	12/27/06	12/1-2/06	12/27-28/06	12/2/06	337	?
NE West Faiman	Trenton, NE	8.0	Rozol	12/1;11/30/06	12/27/06	12/1-2/6	12/27-28/06	12/2-3/06	1621	?
Josh Control	Benkleman, NE	22.2	None	3/9;3/8/07	4/2;4/1/07	3/8-8/07!	4/1-2/07	-	-	-
Sowers	Benkleman, NE	4.8	Rozol	3/8-9/07	4/2;4/1/07	3/8-9/07	4/1-2/07	3/9/07	322	?
Magnani	Benkleman, NE	3.3	Rozol	3/8/07 [no PM]	4/2;4/1/07*	3/8-9/07	none*	3/9/07	101	?
Wiese West	Benkleman, NE	2.1	Rozol	3/8/07	4/2;4/1/07	3/8-9/07	4/1-2/07	3/9/07	174	?
Wiese East	Benkleman, NE	10.6	Rozol	3/8-9/07	4/2;4/1/07	3/8-9/07	4/1-2/07	3/9/07	435**	?

Note 1: A bait application tool called "Prairie Dog Feeder" reportedly was used for all treatments at the Ryan Cemetery, Sowers, and Magnani sites. The same type of equipment was used for some of the burrow treatments at Ryan South, West Faiman, and Wiese East. All applications at Sallee, Hogan, East Lashley, and Wiese West were by hand only (no mechanical equipment used). Calibrations of "Prairie Dog Feeder" equipment nearly always put "dose" amounts between 47 and 53 g (roughly 1.6-1.9 oz) with much greater consistency within calibration checks then between them.

Note 2: At the West Faiman site, 569 additional burrows were treated in an "Area east of draw not in trial but adjacent so we treated them".

Note 3: At the Sowers site, the "66 holes on west" noted on the relevant raw data sheet as having been treated were not included in the sum total of treated burrows reported by Lee and Hyngstrom (2007) in their "Table 2". Presumably, these burrows were outside of the census area for the Sowers site.

*Post-treatment visual counts surveys were done but closed burrows were not because "landowner blew up burrows this am." Landowner reportedly "'plugged all burrows" on 3/31/07 "so they would not move back in" and then "used an exploder 4-1-07 am!"

**Burrow treatments included "297 mechanical" and "138 hand".

Table 2. Visual counts data in 2006-2007 field efficacy trial for Rozol bait (Lee and Hyngstrom, 2007; MRID# 473336-02).

Site Name	Treatment	Pretreat. Visual Count 1st AM	Pretreat. Visual Count 2nd AM	Pretreat. Visual Count 1st PM	Pretreat. Visual Count 2nd PM	Mean of All Four Scan Counts	Highest Pretreat. Count	Post-treat. Visual Count 1st AM	Post-treat. Visual Count 2nd AM	Post-treat. Visual Count 1st PM	Post-treat. Visual Count 2nd PM	Mean of All Four Post-treat. Counts	Highest Post-treat. Count	% Change Pre-Post-Treatment (hi-count)	Adjusted % Change
TNC Control	None	31	40	29	31	32.75	40	36	35	24	26	30.25	36	-10.0%	--
Sallee	Rozol	63	68	42	47	55.00	68	1	0	1	2	1.00	2	-97.1%	-96.7%
Hogan	Rozol	52	57	56	71	59.00	71	2	2	4	6	3.50	6	-91.5%	-90.6%
Ryan Control	None	1	1	3	4	2.25	4	2	2	5	6	3.75	6	50.0%	--
Ryan South	Rozol	12	12	4	5	8.25	12	0	0	2	2	1.00	2	-83.3%	--
Ryan Cemetery	Rozol	4	5	11	12	8.00	12	0	0	0	0	0.00	0	-100.0%	--
NE East Lashley	Rozol	6	5	9	10	7.50	10	0	0	0	0	0.00	0	-100.0%	--
NE West Faiman	Rozol	18	18	29	31	24.00	31	0	0	0	0	0.00	0	-100.0%	--
Josh Control	None	19	21	11	12	15.75	21	34	35	31	33	33.25	35	66.7%	--
Sowers	Rozol	11	11	14	16	13.00	16	2	2	1	1	1.50	2	-87.5%	--
Magnani	Rozol	7	7	--	--	3.50	7	1	1	1	1	1.00	1	-85.7%	--*
Wiese West	Rozol	9	8	8	7	8.00	9	0	0	0	0	0.00	0	-100.0%	--
Wiese East	Rozol	9	10	14	15	12.00	15	0	0	0	0	0.00	0	-100.0%	--

*Post-treatment visual counts surveys were done but closed burrows were not because "landowner blew up burrows this am." Landowner reportedly "plugged plugged all burrows" on 3/31/07 "so they would not move back in" and then "used an exploder 4-1-07 am!"

Table 3. Closed-burrow data in 2006-2007 field efficacy trial for Rozol bait (Lee and Hyngstrom, 2007; MRID# 473336-02).

Site Name	Acreage	Treatment	Burrows Baited	# Burrows Closed for Pretreat. Census	% Baited Burrows Closed for Pretreat. Census	# Census Burrows Closed for Pretreat. Census Transect 1	# Census Burrows Active during Pretreat. Census Transect 1	# Census Burrows Closed for Pretreat. Census Transect 2	# Census Burrows Active during Pretreat. Census Transect 2	Total # Census Burrows Active during Pretreat. Census	% Census Burrows Active during Pretreat. Census	# Burrows Closed for Post-treat. Census	# Census Burrows Closed for Post-treat. Census Transect 1	# Census Burrows Active during Post-treat. Census Transect 1	# Census Burrows Closed for Post-treat. Census Transect 2	# Census Burrows Active during Post-treat. Census Transect 2	Total # Census Burrows Active during Post-treat. Census	% Census Burrows Active during Post-treat. Census	% Change in Burrow Activity from Pretreat.	Adjusted % Change in Burrow Activity from Pretreat.
TNC Control	23.3	None	-	100	-	50	18	50	19	37	37.0%	100	50	9	50	19	28	28.0%	-24.3%	-
Sallee	30.7	Rozol	2680	100	3.7%	50	18	50	27	45	45.0%	100	50	3	50	1	4	4.0%	-91.1%	-88.3%
Hogan	41.5	Rozol	3088	100	3.2%	50	16	50	22	38	38.0%	100	50	2	50	1	3	3.0%	-92.1%	-89.6%
Ryan Control	3.8	None	-	100	-	50	5	50	7	12	12.0%	100	50	4	50	6	10	10.0%	-16.7%	-
Ryan South**	24.4	Rozol	1787	100	5.6%	50	22	50	33	55	55.0%	100	50	0	50	0	0	0.0%	-100.0%	-100.0%
Ryan Cemetery**	14.5	Rozol	1503	100	6.7%	50	28	50	32	60	60.0%	100	50	0	50	0	0	0.0%	-100.0%	-100.0%
NE East Lashley	3.8	Rozol	337	100	29.7%	50	18	50	12	30	30.0%	100	50	1	50	0	1	1.0%	-96.7%	-96.0%
NE West Fairman**	8.0	Rozol	1621	100	6.2%	50	13	50	12	25	25.0%	100	50	0	50	0	0	0.0%	-100.0%	-100.0%
Josh Control	22.2	None	-	100	-	50	14	50	14	28	28.0%	100	50	13	50	15	28	28.0%	0.0%	20.0%
Sowers**	4.8	Rozol	322	100	31.1%	50	9	50	8	17	17.0%	100	50	1	50	0	1	1.0%	-94.1%	-94.1%
Magnani**	3.3	Rozol	101	50	49.5%	25	4	25	8	12	24.0%	-	-	-	-	-	-	-	-	-
Wiese West	2.1	Rozol	174	50	28.7%	25	9	25	10	19	38.0%	50	25	0	25	0	0	0.0%	-100.0%	-100.0%
Wiese East**	10.6	Rozol	435	50	11.5%	25	9	25	11	20	40.0%	50	25	3	25	0	3	6.0%	-85.0%	-85.0%

*Post-treatment visual counts surveys were done but closed burrows were not because "landowner blew up burrows this am." Landowner reportedly "plugged plugged all burrows" on 3/31/07 "so they would not move back in" and then "used an exploder 4-1-07 am!"
**Burrow treatments included "297 mechanical" and "138 hand" on the Wiese East plot, some mecanical and some by hand on Ryan South and West Fairman, and all mechanical on Ryan Cemetery, Sowers, and Magnani.
Note: In the prestreatment census in transect 1 for the Hogan plot, 11 additional burrows were reportedly "opened by rodents", apparently as opposed to "p dogs".

Table 4a. Visible bait post-treatment in 2006-2007 field efficacy trial for Rozol bait (Lee and Hyngstrom, 2007; MRID# 473336-02), October, 2006, baiting.

Site Name	Acreage	Treatment	Burrows Baited	# Burrows Used to Assess Availability	# Days after Baiting	# Holes with Visible Bait	% Holes with Visible Bait	# Holes with Bait at/on Surface	# Holes with Bait 0-6" below Surface	# Holes with Bait >6" below Surface	# Holes with no Visible Bait
Sallee	30.7	Rozol	2680	50	1	24	48.0%	1	0	23	26
				50	2	4	8.0%	0	0	4	46
				50	3	2	4.0%	0	0	2	48
				50	4	3	6.0%	1	0	2	47
				50	5	2	4.0%	0	1	1	48
				50	6	3	6.0%	2	0	1	47
				50	7	1	2.0%	1	0	0	49
Hogan	41.5	Rozol	3088	50	1	14	28.0%	3	3	8	36
				50	2	10	20.0%	1	5	4	40
				50	3	4	8.0%	1	0	3	46
				50	4	3	6.0%	1	0	2	47
				50	5	2	4.0%	0	0	2	48
				50	6	2	4.0%	1	0	1	48
				50	7	0	0.0%	0	0	0	50

Table 4b. Visible bait post-treatment in 2006-2007 field efficacy trial for Rozol bait (Lee and Hyngstrom, 2007; MRID# 473336-02), December, 2006, baiting.

Site Name	Acreage	Treatment	Burrows Baited	# Burrows Used to Assess Availability	# Days after Baiting	# Holes with Visible Bait	% Holes with Visible Bait	# Holes with Bait at/on Surface	# Holes with Bait 0-6" below Surface	# Holes with Bait >6" below Surface	# Holes with no Visible Bait
Ryan South	24.4	Rozol	1787	50	1	34	68.0%	2	20	12	16
				50	2	31	62.0%	2	22	7	19
				50	3	29	58.0%	2	23	4	21
				50	4	20	40.0%	0	17	3	30
				50	5	18	36.0%	0	15	3	32
				50	6	12	24.0%	0	8	4	38
				50	7	10	20.0%	0	8	2	40
Ryan Cemetery	14.5	Rozol	1503	50	1	32	64.0%	2	22	8	18
				50	2	26	52.0%	1	19	6	24
				50	3	21	42.0%	0	18	3	29
				50	4	16	32.0%	1	11	4	34
				50	5	15	30.0%	0	11	4	35
				50	6	13	26.0%	0	11	2	37
				50	7	12	24.0%	0	10	2	38
NE East Lashley	3.8	Rozol	337	50	1	30	60.0%	1	2	27	20
				50	2	12	24.0%	0	4	8	38
				50	3	5	10.0%	0	1	4	45
				50	4	3	6.0%	0	0	3	47
				50	5	3	6.0%	0	0	3	47
				50	6	2	4.0%	0	1	1	48
				50	7	2	4.0%	0	1	1	48
NE West Faiman	8.0	Rozol	1621	50	1	27	54.0%	2	12	13	23
				50	2	27	54.0%	2	14	11	23
				50	3	12	24.0%	0	11	1	38
				50	4	5	10.0%	0	5	0	45
				50	5	4	8.0%	0	3	1	46
				50	6	4	8.0%	0	4	0	46
				50	7	3	6.0%	0	3	0	47

Table 4c. Visible bait post-treatment in 2006-2007 field efficacy trial for Rozol bait (Lee and Hyngstrom, 2007; MRID# 473336-02), March, 2007, baiting.

Site Name	Acreage	Treatment	Burrows Baited	# Burrows Used to Assess Availability	# Days after Baiting	# Holes with Visible Bait	% Holes with Visible Bait	# Holes with Bait at/on Surface	# Holes with Bait 0-6" below Surface	# Holes with Bait >6" below Surface	# Holes with no Visible Bait
Sowers	4.8	Rozol	322	50	1	18	36.0%	0	17	1	32
				50	2	14	28.0%	1	12	1	36
				50	3	1	2.0%	0	1	0	49
				50	4	1	2.0%	0	1	0	49
				50	5	1	2.0%	0	1	0	49
				50	6	1	2.0%	0	1	0	49
				50	7	0	0.0%	0	0	0	50
Magnani	3.3	Rozol	101	50	1	31	62.0%	0	25	6	19
				50	2	27	54.0%	0	22	5	23
				50	3	14	28.0%	0	13	1	36
				50	4	10	20.0%	0	9	1	40
				50	5	7	14.0%	0	7	0	43
				50	6	5	10.0%	0	5	0	45
Wiese West	2.1	Rozol	174	50	1	35	70.0%	0	24	11	15
				50	2	31	62.0%	0	20	11	19
				50	3	31	62.0%	0	20	11	19
				50	4	10	20.0%	0	7	3	40
				50	5	5	10.0%	0	5	0	45
				50	6	2	4.0%	0	2	0	48
				50	7	2	4.0%	0	2	0	48
Wiese East	10.6	Rozol	435	50	1	25	50.0%	0	20	5	25
				50	2	18	36.0%	0	15	3	22
				47*	3	7	14.9%	0	6	1	40
				50	4	5	10.0%	0	3	2	45
				47**	5	1	2.1%	0	0	1	46
				50	6	3	6.0%	0	1	2	47
				50	7	2	4.0%	0	1	1	48

*On this plot on this day, one burrow was not scored for visible bait at all, while two others were scored as having visible bait present but without indicating the depth at which bait was visible.

**On this plot on this day, three burrows were scored as having visible bait; but the depth at which the bait was seen was not indicated.

Table 5a. Amounts of visible bait post-treatment at various depths in 2006-2007 field efficacy trial for Rozol bait (Lee and Hyngstrom, 2007; MRID# 473336-02), October, 2006, baiting.

Site Name	Acreage	Treatment	Burrows Baited	# Burrows Used to Assess Availability	# Days after Baiting	# Holes with Visible Bait	# Holes with no Visible Bait	## of Grains on Surface			## of Grains 0-6" below Surface			## of Grains >6" below Surface		
								<25	25-100	>100	<25	25-100	>100	<25	25-100	>100
Sallee	30.7	Rozol	2680	50	1	24	26	1						11	6	6
				50	2	4	46							1	3	
				50	3	2	48								2	
				50	4	3	47	1							1	1
				50	5	2	48				1					1
				50	6	3	47	2								1
				50	7	1	49	1								
Hogan	41.5	Rozol	3088	50	1	14	36	3			1	2		6		2
				50	2	10	40	1			3	2		2	2	
				50	3	4	46	1						3		
				50	4	3	47	1						2		
				50	5	2	48							2		
				50	6	2	48	1						1		
				50	7	0	50									

Table 5b. Amounts of visible bait post-treatment at various depths in 2006-2007 field efficacy trial for Rozol bait (Lee and Hyngstrom, 2007; MRID# 473336-02), December, 2006, baiting.

Site Name	Acreage	Treatment	Burrows Baited	# Burrows Used to Assess Availability	# Days after Baiting	# Holes with Visible Bait	# Holes with no Visible Bait	## of Grains on Surface			## of Grains 0-6" below Surface			## of Grains >6" below Surface		
								<25	25-100	>100	<25	25-100	>100	<25	25-100	>100
Ryan South	24.4	Rozol	1787	50	1	34	16	1	1		4	6	10	4	3	5
				50	2	31	19	2			9	4	9	4	3	
				50	3	29	21	1	1		9	7	7	3	1	
				50	4	20	30				15	2		3		
				50	5	18	32				13	2		3		
				50	6	12	38				8			4		
				50	7	10	40				8			2		
Ryan Cemetery	14.5	Rozol	1503	50	1	32	18	1		1	2	6	14	3	2	3
				50	2*	26	24		1		5	3	11	1	2	2
				50	3	21	29				6	3	9		1	2
				50	4	16	34	1			6	3	2	2	2	
				50	5	15	35				7	2	2	2	2	
				50	6	13	37				7	4		1	1	
				50	7	12	38				6	4		1	1	

Table 5c. Amounts of visible bait post-treatment at various depths in 2006-2007 field efficacy trial for Rozol bait (Lee and Hyngstrom, 2007; MRID# 473336-02), March, 2007, baiting.

Site Name	Acreage	Treatment	Burrows Baited	# Burrows Used to Assess Availability	# Days after Baiting	# Holes with Visible Bait	# Holes with no Visible Bait	## of Grains on Surface			## of Grains 0-6" below Surface			## of Grains >6" below Surface		
								<25	25-100	>100	<25	25-100	>100	<25	25-100	>100
Sowers	4.8	Rozol	322	50	1	18	32				14	3		1		
				50	2	14	36	1			11	1		1		
				50	3	1	49					1				
				50	4	1	49				1					
				50	5	1	49				1					
				50	6	1	49				1					
				50	7	0	50									
Magnani	3.3	Rozol	101	50	1	31	19				14	9	2	2	4	
				50	2	27	23				11	9	2	2	3	
				50	3	14	36				4	7	2		1	
				50	4	10	40				3	6			1	
				50	5	7	43				2	5				
				50	6	5	45				3	2				
				50	7	3	47				2	1				
Wiese West	2.1	Rozol	174	50	1	35	15				17	7	8	3		
				50	2	31	19				13	7	8	3		
				50	3	31	19				13	7	9	2		
				50	4	10	40				4	3	3			
				50	5	5	45				3	2				
				50	6	2	48				1	1				
				50	7	2	48				1	1				
Wiese East	10.8	Rozol	435	50	1	25	25				17	3	4	1		
				50	2	28	22				12	3	2	1		
				47*	3	7	40				6		1			
				50	4	5	45				2	1	2			
				47**	5	1	46						1			
				50	6	3	47				1		1	1		
				50	7	2	48				1			1		

*On this plot on this day, one burrow was not scored for visible bait at all, while two others were scored as having visible bait present but without indicating the depth at which bait was visible.

**On this plot on this day, three burrows were scored as having visible bait; but the depth at which the bait was seen was not indicated.

Table 6. Comparison among treatment methods on depth of observable bait one day following treatment in Lee and Hyngstrom (2007) study.

Site Name	Month of Treatment	Treatment Method (s)	# Burrows Observed	Depth* at which Bait Was Observed						
				Surface	0-<6 Inches	6 Inches or More	No Bait Observed	% Holes with No Bait Observed	% Holes with No Bait <6 Inches Deep	% Holes w/Bait on Surface or <6 Inches Deep	% Holes with Bait on Surface
Sallee	October, 2006	Hand only	50	1	0	23	26	52.0%	98.0%	2.0%	2.0%
Hogan	October, 2006	Hand only	50	3	3	8	36	72.0%	88.0%	12.0%	6.0%
NE East Lashley	December, 2006	Hand only	50	1	2	27	20	40.0%	94.0%	6.0%	2.0%
Wiese West	March, 2007	Hand Only	50	0	24	11	15	30.0%	52.0%	48.0%	0.0%
Ryan South	December, 2006	Hand and Mechanical	50	2	20	12	16	32.0%	56.0%	44.0%	4.0%
NE West Faiman	December, 2006	Hand and Mechanical	50	2	12	13	23	46.0%	72.0%	28.0%	4.0%
Wiese East	March, 2007	Hand and Mechanical	50	0	20	5	25	50.0%	60.0%	40.0%	0.0%
Ryan Cemetery	December, 2006	Mechanical only	50	2	22	8	18	36.0%	52.0%	48.0%	4.0%
Sowers	March, 2007	Mechanical only	50	0	17	1	32	64.0%	66.0%	34.0%	0.0%
Magnani	March, 2007	Mechanical only	50	0	25	6	19	38.0%	50.0%	50.0%	0.0%

*As only one depth was reported for each burrow for each day, the depth indicated presumably was the shallowest depth at which bait was observed.

CONFIDENTIAL ATTACHMENT

The Confidential Statement of Formula (CSF) dated "23 Jan 2008" filed with the original application to register this product states that it is to be a "100% repackage of 'Rozol Pocket Gopher Bait' EPA Reg. No. 7173-184". The correspondence in formulation between those 2 products was noted by Rachel Callies of Liphatech in an e-mail message of 3/5/08 to Daniel Peacock of IRB. However, the completed application form of 1/23/08 lists 7173-244, "Rozol Pocket Gopher Bait II" as the product to which 7173-EIA is similar or identical in composition and labeling. The CSF of record (dated "Aug 2, 2004") for 7173-244 claims it to be a "100% repackage" of 7173-184.

The CSF of record for 7173-184 appears to be the one dated "27 July 2005". That CSF was the formulation of record for 7173-184 when the prairie dog field efficacy studies reported by Lee and Hyngstrom (2006) were performed. The CSF of 7/27/05 for 7173-184 describes a bait made from "Rozol Rodenticide Technical Powder" (7173-75) at 0.005% nominal concentration, [redacted] at [redacted] The finished bait apparently would consist of [redacted] other ingredients.

The dye used in this product seems likely to correspond to the [redacted] that Palmateer (1979) evaluated for effects on bait palatability. That material was found not to adversely affect the palatability of OPP rat and mouse challenge diet by laboratory strains of the Norway rat and house mouse when the dye was added to the diet at concentrations of [redacted] and [redacted] Those concentrations bracket the level of green dye that is used in 7173-184. See efficacy review of 11/7/05 for 7173-EUI for further discussion of dye terminology and the relevant bioassays. The 7173-EUI product, MAKI MINI PARAFFIN BLOCK II, was registered as 7173-248 on 3/16/08 and canceled on 7/28/08.

Reference

Palmateer, S.D. (1979) Effect of dyes of commensal rodenticides. Unpublished report, Terrestrial and Aquatic Biology Unit, Office of Pesticide Programs, U.S. Environmental Protection Agency, Beltsville, MD, 13 pp.